

# EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF ERIE

ERIE COUNTY MEDICAL CENTER CORPORATION; CATHOLIC HEALTH SYSTEM, INC.; SISTERS OF CHARITY HOSPITAL OF BUFFALO, NEW YORK; MERCY HOSPITAL OF BUFFALO; KENMORE MERCY HOSPITAL; MOUNT ST. MARY'S HOSPITAL OF NIAGARA FALLS; ELLIS HOSPITAL FOUNDATION, INC.; KALEIDA HEALTH; OLEAN GENERAL HOSPITAL; NIAGARA FALLS MEMORIAL MEDICAL CENTER; and ST. LUKE'S CORNWALL HOSPITAL,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC. (f/k/a WATSON PHARMA INC.); ACTAVIS LLC (f/k/a ACTAVIS INC.); JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC. (f/k/a ORTHOMCNEIL-JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA, INC.); NORAMCO, INC.; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS INC.; PAR PHARMACEUTICALS COMPANIES, INC. (f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.); PAR PHARMACEUTICAL, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; AMNEAL PHARMACEUTICALS, LLC; ALLERGAN FINANCE, LLC (f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.); ALLERGAN SALES, LLC; ALLERGAN USA, INC.; PRACTICE FUSION, INC.; ALLSCRIPTS HEALTHCARE SOLUTIONS,

Index No. 806187/2021

**COMPLAINT**

(Deceptive Trade Practices)  
(Negligence)  
(Nuisance)  
(Unjust Enrichment)  
(Fraud and Deceit)  
(Fraudulent Concealment)  
(Civil Conspiracy)  
(Concert of Action)

INC.; AMERISOURCEBERGEN DRUG CORPORATION; ANDA, INC.; CARDINAL HEALTH, INC.; H.D. SMITH, LLC (f/k/a H.D. SMITH WHOLESALE DRUG CO.); HENRY SCHEIN, INC.; CVS PHARMACY, INC.; CVS INDIANA, L.L.C.; CVS ORLANDO FL DISTRIBUTION, L.L.C.; CVS PA DISTRIBUTION, L.L.C.; CVS TN DISTRIBUTION, L.L.C.; CVS VERO FL DISTRIBUTION, L.L.C.; CVS RX SERVICES, INC.; CVS ALBANY, L.L.C.; RITE AID OF NEW YORK, INC.; RITE AID DRUG PALACE, INC.; RITE AID OF MARYLAND, INC. (d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.); WALGREEN CO.; WALGREEN EASTERN CO., INC.; WALMART INC. (f/k/a/ WAL-MART STORES, INC.); WAL-MART STORES EAST, LP; JIM HENNING, DARCI GILLIS, JAMES MCVAY, KIM CADIN; ANTHONY ONESTO; JEFF PALMER; and DOES 1-100,

Defendants.

## TABLE OF CONTENTS

I.	INTRODUCTION.....	2
II.	JURISDICTION AND VENUE .....	3
III.	PARTIES .....	4
A.	Plaintiffs.....	4
B.	Defendants .....	6
1.	Marketing Defendants and Co-Conspirators .....	6
a.	Teva, Actavis, and Associated Companies .....	6
b.	Janssen and Associated Companies .....	8
c.	Endo and Associated Companies.....	9
d.	Abbott Laboratories .....	11
e.	Amneal Pharmaceuticals .....	11
f.	Allergan and Associated Companies.....	11
g.	Practice Fusion .....	12
h.	Sales Representative Defendants .....	13
i.	Mallinckrodt (unnamed co-conspirator).....	15
j.	Purdue (unnamed co-conspirator).....	16
2.	Distributor Defendants .....	20
a.	AmerisourceBergen .....	20
b.	Anda.....	21
c.	Cardinal .....	21
d.	H.D. Smith.....	22
e.	Henry Schein .....	22
3.	National Retail Pharmacies .....	23
a.	CVS.....	23



b.	Rite-Aid .....	24
c.	Walgreens .....	25
d.	Walmart .....	26
4.	Defendants' Agents and Affiliated Persons .....	26
IV.	THE HARM CAUSED BY DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF THEIR LEGAL DUTIES .....	27
A.	Impact of Opioids on New York Hospitals .....	34
B.	Impact of Defendants' Activities on Plaintiffs .....	36
V.	THE MARKETING DEFENDANTS' AND CVS'S FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS .....	38
A.	The Marketing Defendants' False and Deceptive Statements About Opioids .....	41
1.	Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low .....	43
a.	Purdue and Abbott's Misrepresentations Regarding Addiction Risk .....	43
b.	Endo's Misrepresentations Regarding Addiction Risk .....	50
c.	Mallinckrodt's Misrepresentations Regarding Addiction Risk .....	52
2.	Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed .....	53
3.	Falsehood #3: Signs of Addictive Behavior are "Pseudoaddiction" Requiring More Opioids .....	55
4.	Falsehood #4: Addicted Patients are "Untrustworthy" "Abusers." .....	57
5.	Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering .....	58
6.	Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk .....	58
7.	Falsehood #7: Long-term Opioid Use Improves Functioning .....	60
8.	Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids .....	63
9.	Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief .....	66
10.	Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse .....	70

a.	Purdue’s Deceptive Marketing of Reformulated OxyContin and Hysingla ER.....	71
b.	Endo’s Deceptive Marketing of Reformulated Opana ER .....	73
c.	Mallinckrodt’s Misrepresentations of Exalgo and Xartemis XR as Abuse Deterrents. ....	77
B.	The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels.....	78
1.	The Marketing Defendants Used “Detailers” To Directly Disseminate Their Misrepresentations to Prescribers. ....	79
2.	The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use. ....	81
a.	American Pain Foundation.....	83
b.	American Academy of Pain Medicine and the American Pain Society .....	86
c.	Federation of State Medical Boards .....	88
d.	The Joint Commission and the Pain & Policy Study Group of the University of Wisconsin.....	90
e.	Alliance for Patient Access .....	94
f.	U.S. Pain Foundation .....	97
g.	American Geriatrics Society .....	98
h.	American Chronic Pain Association .....	100
i.	National Pharmaceutical Council .....	100
3.	The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use. ....	101
a.	Dr. Russell Portenoy .....	103
b.	Dr. Lynn Webster .....	105
c.	Dr. Perry Fine.....	106
d.	Dr. Scott Fishman.....	108
4.	The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs.....	109

5.	The Marketing Defendants Used Branded Advertising to Promote Their Products to Doctors and Consumers.....	111
6.	The Marketing Defendants Used Unbranded Advertising to Promote Opioid Use for Chronic Pain Without FDA Review.....	112
7.	The Marketing Defendants Funded, Edited, and Distributed Publications That Supported Their Misrepresentations. ....	112
8.	The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.....	113
9.	The Marketing Defendants Conspired with Practice Fusion to Spread Their Deceptive Messages. ....	114
C.	The Marketing Defendants Directly Targeted Hospitals.....	117
D.	The Marketing Defendants' Goal Was for More Patients to Take More Opioids at Higher Doses for Longer Periods of Time. ....	118
1.	Increasing the Patient Population.....	118
a.	The Marketing Defendants Focused on Elderly Patients.....	118
b.	The Marketing Defendants Focused on "Opioid-Naïve" Patients. ....	119
2.	Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer .....	119
E.	The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic. ....	120
1.	The Marketing Defendants' Influence Dramatically Expanded Opioid Prescribing and Use.....	120
2.	The Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.....	122
F.	Each of the Marketing Defendants Made Materially Deceptive Statements and Concealed Material Facts. ....	123
1.	Purdue .....	123
2.	Abbott.....	128
3.	Endo.....	137
4.	Janssen and J&J.....	141
a.	Janssen's Misrepresentations Concerning Addiction Risk.....	143

b.	J&J's Activities Through Tasmanian Alkaloids and Noramco.....	151
c.	Janssen's Unbranded Promotion of Opioids and Action in Concert With its Co-Conspirators.....	154
d.	FDA Warnings about Duragesic .....	158
e.	Janssen and J&J's Losses in Recent Litigation.....	159
5.	Teva .....	161
a.	Teva's Marketing in New York.....	162
b.	Teva and Cephalon Fraudulently Marketed Actiq.....	167
i.	Approval and Marketing of Actiq.....	167
ii.	Actiq Marketing to Doctors.....	168
iii.	Actiq Marketing to Patients .....	171
iv.	Auditors Cannot Stop Off-Label Marketing.....	172
v.	2008 Actiq Settlements.....	173
c.	Cephalon Fraudulently Marketed Fentora. ....	173
d.	FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora.....	174
e.	Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses.....	175
f.	Teva Loses Summary Judgment Motions in the MDL.....	176
6.	Actavis.....	176
a.	Marketing of Kadian and Brand Name Products .....	176
b.	Marketing of Generic Products .....	177
7.	Mallinckrodt .....	179
8.	Practice Fusion.....	180
9.	The Sales Representative Defendants .....	180
VI.	FRAUDULENT MARKETING CONDUCT BY CVS.....	181

A.	CVS’s Work with Purdue.....	181
B.	CVS’s Work with Endo.....	184
C.	CVS’s Work with Actavis.....	185
VII.	DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS.....	185
A.	All Defendants Have, and Have Breached, Duties to Guard Against, Prevent, and Report Suspicious Orders and Unlawful Diversion.....	186
B.	Defendants Used Trade and Other Organizations. ....	191
1.	Pain Care Forum.....	191
2.	Healthcare Distribution Alliance.....	192
C.	Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.....	196
D.	Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers.....	197
E.	Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion. ....	203
F.	Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement. ....	205
G.	The Marketing Defendants’ Failed to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders.....	208
1.	Mallinckrodt .....	210
2.	Teva .....	212
3.	Janssen.....	214
H.	The Distributor Defendants Unlawfully Distributed Opioids. ....	214
I.	The Distributor Defendants Breached Their Duties.....	215
1.	Inadequate Scrutiny of Customers.....	219
2.	Failure to Detect, Block, and Report Suspicious Orders.....	220

3.	Failure to Adequately Maintain Accessible Data Concerning Customers and Prescribers .....	221
4.	Failure to Report Violations to Government Authorities .....	222
J.	Each of the Distributor Defendants Engaged in Wrongful Conduct.....	223
1.	Cardinal .....	223
a.	Cardinal’s Flawed Written Policies Enabled Opioid Diversion.....	223
b.	Cardinal Failed to Effectively Prevent Diversion in Practice.....	223
c.	Cardinal Was Put on Notice of its Wrongful Conduct. ....	226
2.	AmerisourceBergen .....	228
a.	AmerisourceBergen’s Flawed Written Policies Enabled Opioid Diversion.....	228
b.	AmerisourceBergen Failed to Effectively Prevent Diversion in Practice.....	230
c.	AmerisourceBergen Was Put on Notice of its Wrongful Conduct. ....	232
3.	Anda .....	232
4.	H.D. Smith .....	234
a.	H.D. Smith’s Opioid Activity in New York .....	234
b.	H.D. Smith’s Flawed Monitoring Policies and Programs Enabled Opioid Diversion.....	234
c.	H.D. Smith Participated in Front Groups. ....	237
d.	H.D. Smith’s Opioid Settlement.....	237
e.	H.D. Smith is Denied Summary Judgment in the MDL.....	238
5.	Henry Schein .....	238
a.	Henry Schein’s Activity in New York.....	238
b.	Henry Schein’s Inadequate SOM Program .....	238
c.	Henry Schein Is Denied Summary Judgment in the MDL.....	239
K.	The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.....	240

I.	Repeated Admonishments and Fines Did Not Stop the Distributor Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion.	242
M.	The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.	242
I.	CVS.	247
a.	CVS Flooded New York With Opioids.	247
b.	CVS Failed to Establish an Effective SOM System.	247
i.	CVS Knows It Needs an SOM System and Has Existing Capabilities to Create One.	247
ii.	CVS's Distribution Network Systems	249
iii.	CVS's Automated System for SOM	250
iv.	CVS Implemented an Integrated Systems to Track Profits.	251
c.	CVS Worked with Other Defendants to Increase Profits and Disseminate False Information.	252
d.	Multiple Enforcement Actions Against CVS Confirm Its Compliance Failures.	252
2.	Walgreens.	254
a.	Walgreens Flooded New York With Opioids.	254
b.	Walgreens Designed and Implemented an Entirely Inadequate SOM System.	254
c.	Walgreens Knew Its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.	257
d.	Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.	258
e.	Even As It Rolled Out Its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.	258
f.	Walgreens Failed to Put in Place Adequate Policies to Guard Against Diversion at the Pharmacy Level.	262

g.	Walgreens Assumed Greater Responsibility for Controlling Against Diversion by Discouraging Outside Vendors from Exercising Their Own Oversight.....	263
h.	Walgreens Failed to Maintain Effective Controls Against Diversion in New York.....	265
i.	Walgreens's Performance Metrics Put Profits Before Safety.....	266
j.	Walgreens Entered Into Joint Ventures that Further Undermined Its Outside Vendors' Incentive to Conduct Due Diligence While Increasing Its Own Access to Information.....	268
k.	Multiple Enforcement Actions Against Walgreens Confirm Its Compliance Failures.....	269
3.	Walmart.....	271
4.	Rite Aid.....	284
VIII.	ADDITIONAL ALLEGATIONS PERTAINING TO PUNITIVE DAMAGES .....	291
IX.	COLLECTIVE CONDUCT ALLEGATIONS.....	292
A.	Conspiracy Allegations.....	292
1.	Conspiracy Among the Marketing Defendants .....	292
2.	Conspiracy Among the Marketing Defendants and the Supply Chain Defendants .....	295
B.	Joint Enterprise Allegations.....	296
X.	TOLLING AND FRAUDULENT CONCEALMENT.....	296
XI.	CLAIMS FOR RELIEF .....	298
	FIRST CLAIM FOR RELIEF.....	298
	SECOND CLAIM FOR RELIEF .....	301
A.	Defendants Owed a Duty of Care.....	301
B.	Defendants Breached Their Duty Of Reasonable Care .....	302
1.	Negligent Marketing (Marketing Defendants, Sales Representative Defendants, and CVS).....	302



2.	Negligent Distribution (Marketing and Supply Chain Defendants) and Negligent Dispensing (National Retail Pharmacies).....	303
C.	Defendants’ Breaches of Care Were Intentional, Willful, Wanton, Reckless, and/or Grossly Negligent.....	306
D.	Causation and Damages .....	307
	THIRD CLAIM FOR RELIEF.....	308
	FOURTH CLAIM FOR RELIEF .....	311
	FIFTH CLAIM FOR RELIEF .....	313
	SIXTH CLAIM FOR RELIEF.....	319
	SEVENTH CLAIM FOR RELIEF .....	321
	EIGHTH CLAIM FOR RELIEF .....	323
XII.	PRAYER FOR RELIEF .....	324
XIII.	JURY DEMAND .....	325

### COMPLAINT

Plaintiffs Erie County Medical Center Corporation; Catholic Health System, Inc.; Sisters of Charity Hospital of Buffalo, New York; Mercy Hospital of Buffalo; Kenmore Mercy Hospital; Mount St. Mary's Hospital of Niagara Falls; Ellis Hospital Foundation, Inc.; Kaleida Health; Olean General Hospital; Niagara Falls Memorial Medical Center; and St. Luke's Cornwall Hospital (collectively, "Plaintiffs") bring this Complaint against Defendants Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Watson Laboratories, Inc.; Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.); Actavis LLC (f/k/a Actavis Inc.); Johnson & Johnson; Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc.); Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals Inc.; Par Pharmaceuticals Companies, Inc. (f/k/a Par Pharmaceutical Holdings, Inc.); Par Pharmaceutical, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.; Amneal Pharmaceuticals, LLC; Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.); Allergan Sales, LLC; Allergan USA, Inc.; Practice Fusion, Inc.; Allscripts Healthcare Solutions, Inc.; AmerisourceBergen Drug Corporation; Anda, Inc.; Cardinal Health, Inc.; H.D. Smith, LLC (f/k/a H.D. Smith Wholesale Drug Co.); Henry Schein, Inc.; CVS Pharmacy, Inc.; CVS Indiana, L.L.C.; CVS Orlando FL Distribution, L.L.C.; CVS PA Distribution, L.L.C.; CVS TN Distribution, L.L.C.; CVS Vero FL Distribution, L.L.C.; CVS Rx Services, Inc.; CVS Albany, L.L.C.; Rite Aid of New York, Inc.; Rite Aid of Maryland, Inc. (d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.); Rite Aid Drug Palace, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc.; Walmart Inc. (f/k/a/ Wal-Mart Stores, Inc.); Wal-Mart Stores East, LP; Jim Henning; Darci Gillis; James Mcvay; Kim Cadin; Anthony Onesto; Jeff Palmer; and Does 1-100 (collectively "Defendants"), asserting claims of negligence, wanton misconduct, public nuisance, unjust enrichment, fraud and deceit, fraudulent concealment, and civil conspiracy seeking judgment against Defendants and in favor of Plaintiffs; compensatory damages; treble damages; punitive damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief, and allege as follows:

## **I. INTRODUCTION**

1. Plaintiffs operate hospitals that provide acute care throughout New York, including treatment for opioid-dependent patients and patients suffering from opioid-related conditions.<sup>1</sup> These patients routinely seek services at Plaintiffs' emergency departments and occupy beds in Plaintiffs' hospitals. Hospitals are legally and morally compelled to act and treat all of these patients, regardless of the price.

2. Defendants are the manufacturers, distributors, and dispensers of prescription opioids. By flooding Plaintiffs' communities with opioids, by pushing false narratives surrounding the safety of opioids, and by failing to take steps to prevent diversion of opioids, they have created an epidemic of misuse, abuse, addiction, and death.

3. Drug companies manufactured opioids, aggressively pushed highly addictive opioids for the long-term treatment of chronic pain and falsely represented to doctors that their patients would only rarely succumb to drug dependence. The campaigns of these companies were directed at doctors and hospitals and induced them to purchase and prescribe what the manufacturers knew were drugs prone to dangerous misuse. Ignoring the human cost of opioid dependency, these companies turned patients into addicts for profit.

4. Pharmaceutical distributors and chain pharmacies participated in the drug companies' misconduct by repeating and reinforcing the false message that long-term opioid treatment for chronic pain was safe and effective with a low risk of addiction. Moreover, they repeatedly breached their legal duties to monitor, detect, investigate, report, and refuse to fill suspicious opioid orders and prescriptions, enabling opioids to flow out into Plaintiffs' communities.

5. While Defendants profited, Plaintiffs paid the cost of their misdeeds. The average cost of providing care for patients diagnosed with an opioid use disorder is eight times higher than for

---

<sup>1</sup> "Opioid-related conditions" include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or other conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs' records as related to opioid use and abuse.

those without an opioid use disorder.<sup>2</sup> Patients must still be provided with complete care, but private and government insurance does not cover these increased costs.

6. By providing care to patients who would not have had opioid-related conditions but for Defendants' misconduct, hospitals have mitigated the consequences of Defendants' illegal activities, thereby permitting Defendants to perpetuate their wrongful scheme.

7. Plaintiffs bring this civil action to recover what they have lost as a result of providing care to patients with opioid-use disorders and opioid-related conditions that were acquired as a direct and proximate result of Defendants' false, deceptive, and unfair marketing, distribution, and dispensing of opioids.

## **II. JURISDICTION AND VENUE**

8. Pursuant to Article VI, section 7 of the Constitution of the State of New York, this Court has subject matter jurisdiction over this action because Plaintiffs' claims sound in law and/or equity.

9. This Court has personal jurisdiction over Defendants Par Pharmaceutical, Inc.; Par Pharmaceuticals Companies, Inc.; and Henry Schein, Inc. because their principal places of business are located in New York.

10. This Court has personal jurisdiction over Defendants Walgreen Eastern Co., Inc.; CVS Rx Services, Inc.; Rite Aid of New York, Inc.; and Walgreen Eastern Co., Inc. because they are incorporated in New York.

11. This Court has personal jurisdiction over Defendants in that they transacted business within the state and/or contracted to supply goods or service in the state through the manufacture, sale, distribution, and/or dispensing of prescription opioids, and/or committed tortious acts and/or omissions within New York as described in this Complaint, and/or committed tortious acts and/or omissions without New York while regularly doing business in New York and deriving substantial revenue from goods or services used or rendered in New York as described in this Complaint, and/or

---

<sup>2</sup> Alen G. White, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, 11 J. Managed Care Pharmacy 469 (2005).

own, use, or possess real property situated within New York.

12. This Court has personal jurisdiction over Defendants because they purposefully directed their actions towards New York, voluntarily submitted to the jurisdiction of New York when obtaining a manufacturer, pharmacy, and/or distributor license and so invoking the protection of New York laws.

13. Defendants have the requisite minimum contacts with New York necessary to constitutionally permit this Court to exercise jurisdiction.

14. Venue lies in this forum pursuant to section 503(a) of the New York Civil Practice Law and Rules because a substantial part of the events or omissions giving rise to this claim occurred in Erie County, New York including the marketing of opioids to health care providers and the general public, the distribution of opioids to pharmacies in Erie County, and the dispensing of opioids to the public from those pharmacies.

15. Venue is also proper in this forum pursuant to section 503(a), (c) of the New York Civil Practice Law and Rules because Plaintiffs Erie County Medical Center Corporation, Catholic Health System, Inc., Sisters of Charity Hospital of Buffalo, New York, Mercy Hospital of Buffalo, Kenmore Mercy Hospital, and Kaleida Health have their principal places of business in Erie County.

16. This action is non-removable because there is incomplete diversity of residents, because there are Defendants with New York citizenship for purposes of federal subject matter jurisdiction, and because no substantial federal question is presented.

### **III. PARTIES**

#### **A. Plaintiffs**

17. Plaintiff Erie County Medical Center Corporation is a public benefit corporation formed and existing under the laws of the state of New York that operates as a hospital in Buffalo, New York.

18. Plaintiff Catholic Health System, Inc. is a domestic not-for-profit corporation that operates four hospitals: Kenmore Mercy Hospital in Kenmore, New York; Mercy Hospital of Buffalo

in Buffalo, New York; Mount St. Mary's Hospital of Niagara Falls in Lewiston, New York; and Sisters of Charity Hospital of Buffalo in Buffalo, New York and Cheektowaga, New York.

19. Plaintiff Sisters of Charity Hospital of Buffalo, New York is a domestic not-for-profit corporation.

20. Plaintiff Mercy Hospital of Buffalo is a domestic not-for-profit corporation.

21. Plaintiff Kenmore Mercy Hospital is a domestic not-for-profit corporation.

22. Mount St. Mary's Hospital of Niagara Falls is a domestic not-for-profit corporation.

23. Plaintiff Ellis Hospital Foundation, Inc., is a domestic not-for-profit corporation that operates two hospitals: Ellis Hospital in Schenectady, New York; and Bellevue Women's Center in Niskayuna, New York.

24. Plaintiff Kaleida Health is a domestic not-for-profit corporation that operates four hospitals: Buffalo General Medical Center in Buffalo, New York; DeGraff Medical Park in North Tonawanda, New York; Millard Fillmore Suburban Hospital in Williamsville, New York; and Oishei Children's Hospital in Buffalo, New York. Prior to 2020, Kaleida Health owned and operated DeGraff Memorial Hospital in North Tonawanda, New York. DeGraff Memorial Hospital is now known as DeGraff Medical Park and is currently owned and operated by Kaleida Health.

25. Plaintiff Olean General Hospital is a domestic not-for-profit corporation that operates as a hospital in Olean, New York.

26. Plaintiff Niagara Falls Memorial Medical Center is a domestic not-for-profit corporation that operates a hospital in Niagara Falls, New York.

27. Plaintiff St. Luke's Cornwall Hospital is a domestic not-for-profit corporation that operates St. Luke's Cornwall in Newburgh, New York, and St. Luke's Cornwall in Cornwall, New York.

**B. Defendants**

**1. Marketing Defendants and Co-Conspirators**

**a. Teva, Actavis, and Associated Companies**

28. Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. is traded on the New York Stock Exchange (NYSE: TEVA). In its most recent Form 10-K filed with the Securities and Exchange Commission, Teva Ltd. stated that it is the leading generic drug company in the United States. Teva Ltd. operates globally, with significant business transactions in the United States. In 2018, its gross profit from North American operations was \$4.979 million.

29. Defendant Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In October 2011, Teva Pharmaceutical Industries, Ltd. acquired Cephalon, which became a wholly owned subsidiary of Teva Ltd.

30. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a wholly owned subsidiary of Teva Ltd.

31. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States through its “specialty medicines” division. Teva USA and Cephalon worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA and directs physicians to contact Teva USA to report adverse events. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo.<sup>3</sup> Teva USA’s parent company, Teva Pharmaceuticals Industries, Ltd., lists Cephalon and Teva USA’s sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition –

---

<sup>3</sup> See, e.g., ACTIQ, <http://www.actiq.com> (displaying logo at bottom-left) (last accessed August 1, 2018).

attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora.<sup>4</sup> Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”<sup>5</sup> Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”<sup>6</sup> In 2008, Cephalon pled guilty to a criminal violation of the federal Food, Drug, and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay a \$425 million fine.<sup>7</sup>

32. Teva Ltd., Teva USA, and Cephalon are referred to herein as “Teva.”

33. Defendant Watson Laboratories, Inc. (“Watson”) is a Nevada corporation with its principal place of business in Corona, California.

34. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) (“Actavis Pharma”) is a Delaware corporation with its principal place of business in New Jersey.

35. Defendant Actavis LLC (f/k/a Actavis Inc.) (“Actavis LLC”) is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Watson, Actavis Pharma, and Actavis LLC are collectively referred to as “Actavis.”

36. Teva Ltd. acquired ownership of Actavis in 2016. Prior to that transaction, Actavis was owned by Defendant Allergan plc.

<sup>4</sup> Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), [http://annualreports.com/HostedData/AnnualReportArchive/t\\_NASDAQ\\_Teva\\_2012.pdf](http://annualreports.com/HostedData/AnnualReportArchive/t_NASDAQ_Teva_2012.pdf).

<sup>5</sup> *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, ACTIQ PI/Med Guide, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020747s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf) (last accessed August 1, 2018).

<sup>6</sup> *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/021947s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf) (last accessed August 1, 2018).

<sup>7</sup> Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.



37. Actavis made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, and assisting in post-marketing safety surveillance, but in fact for deceptively promoting and maximizing the use of opioids.

**b. Janssen and Associated Companies**

38. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

39. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

40. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opium processing. It makes active pharmaceutical ingredients ("APIs") for opioid painkillers.

41. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

42. Janssen made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, and assisting in post-marketing safety surveillance, but in fact for deceptively promoting and maximizing the use of opioids.

43. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson

Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, and assisting in post-marketing safety surveillance, but in fact for deceptively promoting and maximizing the use of opioids.

**c. Endo and Associated Companies**

44. Defendant Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

45. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

46. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is wholly owned subsidiary of Par Pharmaceuticals Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

47. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. It is the parent company of Par Pharmaceutical, Inc.

48. Par Pharmaceutical, Inc. and Par Pharmaceuticals Companies, Inc. are referred to collectively as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. Endo Health Solutions, Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., and Par Pharmaceuticals Companies, Inc. are collectively referred to herein as "Endo".

49. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone, and hydrocodone in the United States. Opioids made up roughly \$403 million of

Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo's total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C due to abuse of the drug after its reformulation from a nasal spray to an injectable.<sup>8</sup> This was the first time the agency had ever moved to pull an opioid medication from sale. In response to the FDA's request, Endo removed Opana ER from the market in July 2017.<sup>9</sup> Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

50. Endo invested heavily in Front Groups and Key Opinion Leaders ("KOLs") in support of its Opana ER opioid product, and in so doing, recognized the effect of such investments on its sales and marketing. Its business plan included "utiliz[ing] existing and newly trained specialist speakers" in an effort to "[p]rovide a platform for dialogue between pain specialists" and the pain physician community to discuss Opana ER.<sup>10</sup>

51. Since 2013, Endo has provided more than \$28 million to physicians, as well as sponsored research and development initiatives.<sup>11</sup> Endo also heavily invested in Front Groups focused on pain issues, including \$5.9 million to the American Pain Foundation, \$4.2 million to the American Pain Society, \$1.3 million to the American Academy of Pain Medicine, and \$369,000 to the Federation of State Medical Boards.<sup>12</sup>

<sup>8</sup> Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

<sup>9</sup> Press Release, Endo International plc, Endo Provides Update on Opana ER (July 6, 2017), <http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opana-er> (hereinafter "Endo Provides Update on Opana ER").

<sup>10</sup> Endo Pharmaceuticals, 2008 – 2012 Opana ER Business Plan PowerPoint Presentation (Nov. 29, 2007), SFC-00025042, *et seq.*, at 25073, <https://www.finance.senate.gov/download/sfc-00025042>.

<sup>11</sup> U.S. Senate Fin. Comm., *Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and other Tax-Exempt Entities* (Dec. 16, 2020), at 7, available at <https://www.finance.senate.gov/imo/media/doc/2020-12-16%20Finance%20Committee%20Bipartisan%20Opioids%20Report.pdf> (hereinafter "*December 2020 Senate Bipartisan Opioids Report*"). Purdue provided \$89 million to physicians and sponsored research during the same period. *Id.*

<sup>12</sup> *Id.*

**d. Abbott Laboratories**

52. Defendant Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as “Abbott.”

53. Abbott marketed OxyContin and other Purdue opioids to hospitals and their doctors throughout the United States under a co-promotion agreement with Purdue.

**e. Amneal Pharmaceuticals**

54. Defendant Amneal Pharmaceuticals, LLC (“Amneal”) is a Delaware limited liability company with its principal place of business in New Jersey.

55. At all relevant times, Amneal has sold prescription drugs including opioids in New York and across the United States.

**f. Allergan and Associated Companies**

56. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Shares of Allergan plc are traded on the New York Stock Exchange (NYSE: AGN). In its most recent Form 10-K filed with the SEC, Allergan plc stated that it does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which together generated nearly 80% of the company’s \$15.8 billion in net revenue in 2018.

57. Before Actavis was sold to Teva Ltd. in August 2016, Actavis was part of the same corporate family as Allergan plc, an Irish drug company, and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergan plc and Actavis.

58. Defendant Allergan plc has, at all times, exercised control over these marketing and sales efforts and profits from the sale of its subsidiaries’ products ultimately inure to its benefit, including those sales by Actavis during the period of its ownership and control by Allergan plc. Allergan plc is or has been in the business of manufacturing, selling, promoting, and/or distributing

both brand name and generic opioids throughout the United States, including to Plaintiffs in New York.

59. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly-owned subsidiary of Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC) acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

60. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and, in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc. The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

61. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

62. Allergan plc; Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc. are collectively referred to as "Allergan."

**g. Practice Fusion**

63. Defendant Practice Fusion, Inc. was a Delaware corporation with headquarters in San Francisco, California.

64. Defendant Allscripts Healthcare Solutions, Inc. ("Allscripts") is a Delaware corporation with headquarters in Chicago, Illinois. Allscripts acquired Practice Fusion, Inc. in a merger completed February 13, 2018.

65. Practice Fusion, Inc. and Allscripts are referred to as “Practice Fusion” throughout the Complaint.

66. Practice Fusion provided cloud-based electronic health records (“EHR”) to traditionally hard-to-reach, small, independent physician practices without charge.

#### **h. Sales Representative Defendants**

67. Defendants Jim Henning, Darci Gillis, James Mcvay, Kim Cadin, Anthony Onesto, and Jeff Palmer (collectively, the “Sales Representative Defendants”) are all residents of New York.

68. Defendant Jim Henning was a Senior Pain Care Specialist for Teva Pharmaceuticals from 2012 to 2016, and his territory included Brooklyn, Queens, and Long Island, New York. Defendant Henning earned numerous awards for his prolific marketing of Fentora. In 2013, he was awarded second place for the Fentora Growth Award by the National Sales Director for outstanding achievement in volume growth and percentage growth. In 2014, he was awarded winner of the Pain Care “Make it Happen” contest by the Vice President of Sales. In 2014 and 2015, he earned the top ranked Pain Care Representative in the nation honors for Fentora. Defendant Henning has held various regional and national advisory roles in his capacity as a pain management sales representative.

69. Defendant Darci Gillis was a Hospital Specialty Representative for Johnson & Johnson from 2000 to 2003 in the Brooklyn, New York area. Defendant Gillis marketed the opioid Duragesic. In the first year of her employment, she moved her territory ranking from #251 to #5 nationally. She also held the #1 ranking for the Northeast region. This earned her the 2001 Winner of Individual Field Sales Director Award. In 2003, she held the 7th highest Duragesic market share in the entire country. Defendant Gillis was one of two sales representatives selected by Johnson & Johnson to attend the Management Development Program from the Northeast Region in 2002. She was also nominated to attend the Johnson & Johnson Women’s Leadership Conference. From 2003 to 2011, she worked as a Specialty CNS Sales Representative for Cephalon, where she marketed the opioid Actiq in the Greater New York City area. In 2004, she was named Winner of Regional Sales Contest for generating the largest number of new Actiq prescribers.

70. Defendant James Mcvay is a Territory Sales Representative for Cephalon Inc., where he has worked since 2001. His sales territory includes New York. Prior to this role, Defendant Mcvay was a Hospital Sales Specialist for Purdue Pharma from 1991 to 2001. In his time with Purdue, he participated in the launch of OxyContin in 1996 and achieved a rank of 27 out of 596 representatives for his sales of the drug. He received a sales growth recognition award for OxyContin sales in 1998 and 1999. He was responsible for selling OxyContin to the hospital market and organized several regional "Pain Day" speaker symposiums with Roswell Park and Hospice Buffalo. Following his decade of marketing OxyContin with Purdue, he transitioned to Cephalon, where he marketed Actiq in New York and served as a member of the pain care sales force from 2001 to 2005. He takes credit for transforming a "low performing territory" that was ranked last in 2001 to a ranking of 3rd out of 356 territories in 2003.

71. Defendant Kim Cadin was a Territory Sales Specialist for Cephalon from 2008 to 2012, and her territory included the Albany, New York area. In 2009, she ranked 5th out of 110 sales representatives for Fentora. In 2010, she ranked 10th. At a 2009 East Regional meeting, she conducted a presentation on her success and "best practices" for growing Fentora sales.

72. Defendant Anthony Onesto is a Specialty Sales Executive for Endo Pharmaceuticals, and his territory includes New York. Defendant Onesto marketed Opana and was elected to the Opana Field Advisory Board from 2008 to 2010. He was responsible for launching Opana ER in his district and was the Opana ER district product champion from 2008 to 2011. He led regional conference calls to promote a "consultative selling approach" for Opana ER in 2010. In 2011, he was a Circle of Excellence Winner ranked #5 in the nation. In 2012, he was elected to the Pain Solutions Field Advisory Board.

73. Defendant Jeff Palmer was a Specialty Sales Consultant for Endo Pharmaceuticals from 2006 to 2016, and his territory included the Staten Island, New York area. He sold Opana and Opana ER and won awards for his sales, including the Circle of Excellence award, the Regional Impact Award, and Representative of the Year Award for the Northeast Region.

**i. Mallinckrodt (unnamed co-conspirator)**

74. Mallinckrodt LLC, Mallinckrodt plc, and SpecGx LLC (collectively, “Mallinckrodt”) manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States, including to Plaintiffs in New York. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

75. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA’s entire annual quota for controlled substances that it manufactures, and its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.<sup>13</sup>

76. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (hydromorphone hydrochloride, extended release), Roxicodone (oxycodone hydrochloride), Xartemis XR (oxycodone hydrochloride and acetaminophen), Methadose (methadone hydrochloride), generic morphine sulfate extended release, morphine sulfate oral solution, fentanyl transdermal system, oral transmucosal fentanyl citrate, oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride, hydromorphone hydrochloride, extended release, oxymorphone hydrochloride, and methadone hydrochloride. Schedule III: buprenorphine and naloxone. Unscheduled: naltrexone hydrochloride.

77. Mallinckrodt made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, and assisting in post-marketing safety surveillance, but in fact for deceptively promoting and maximizing the use of opioids.

---

<sup>13</sup> Mallinckrodt plc, 2016 Annual Report (Form 10-K), <http://www.mallinckrodt.com/investors/annual-reports> (hereinafter, “Mallinckrodt 2016 Annual Report”).



**j. Purdue (unnamed co-conspirator)**

78. Although not named as Defendants in this matter, Purdue Pharma, L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company (collectively, “Purdue”) participated with Defendants in the misconduct alleged in this action.

79. The following individuals, all members of the Sackler family that beneficially owns Purdue, have served on Purdue’s Board of Directors:

- a. Richard Sackler (at all pertinent times until 2018), a resident of Florida;
- b. Beverly Sackler (all pertinent times until 2017), a resident of Connecticut;
- c. David Sackler (2012 – 2018), a resident of New York;
- d. Ilene Sackler Lefcourt (all pertinent times), a resident of New York;
- e. Jonathan Sackler (all pertinent times), a resident of Connecticut;
- f. Kathe Sackler (all pertinent times), a resident of Connecticut;
- g. Mortimer D.A. Sackler (all pertinent times), a resident of New York<sup>14</sup>; and
- h. Theresa Sackler (all pertinent times until 2018), a resident of the United Kingdom.<sup>15</sup>

80. These individuals (collectively, the “Sacklers”) are not named as defendants in this matter. However, the Sacklers controlled Purdue’s misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, the Sacklers, at all pertinent times, constituted a majority of the Board, which gave them full power over Purdue. They directed and otherwise participated in Purdue’s deceptive sales and marketing practices, sending hundreds of orders to executives and other employees.

81. At all pertinent times, at least through the end of 2018, the Sacklers controlled Purdue’s

---

<sup>14</sup> References to “Mortimer D.A. Sackler” in this Complaint are to Mortimer David Alfons Sackler. Mortimer Sackler’s father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

<sup>15</sup> Beverly Sackler left the Board in 2017. Richard, David and Theresa Sackler left the Board in 2018. Jonathan Sackler, Ilene Sackler Lefcourt, Kathe Sackler, and Mortimer D.A. Sackler remain on the Board.

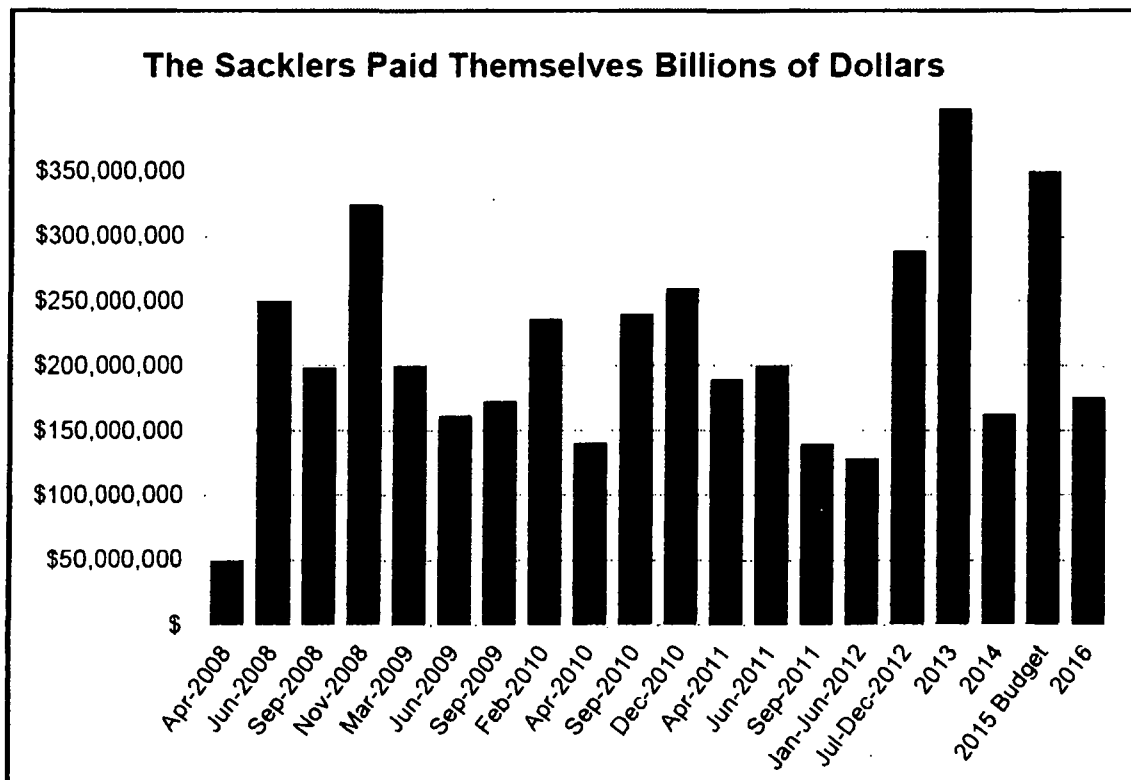
deceptive sales campaign. They directed the company to hire hundreds of sales representatives to visit doctors thousands of times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors face-to-face and supervise representatives in person. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sacklers; Mortimer D.A. Sackler asked about launching a generic version of OxyContin to “capture more cost sensitive patients;” Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert; and Jonathan Sackler wanted to study changes in market share for opioids based on dose strength.

82. The Sacklers concealed their extensive involvement at all costs. In 2000, they were warned that a reporter was “sniffing about the OxyContin abuse story.” The Sacklers put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that “deflects attention away from the company owners.” More recently, in November 2016, staff prepared statements to the press denying the Sacklers’ involvement in Purdue. The draft claimed: “Sackler family members hold no leadership roles in the companies owned by the family trust.” A staff member reviewing the draft knew what was up and commented with apparent sarcasm: “Love the . . . statement.” Staff eventually told the press: “Sackler family members hold no management positions.” Some employees worried about the deception. When journalists asked follow-up questions about the Sacklers, communications staff deliberated about whether to repeat the “no management positions” claim. They double-checked that Purdue’s top lawyers had approved the statement. They then arranged for one of the Sacklers’ foreign companies to issue it, so U.S. employees would not be

blamed: “The statement will come out of Singapore.”

83. From the money that Purdue collected as a result of its wrongful conduct, the Sacklers paid themselves and their family billions of dollars. From the 2007 convictions (of certain officers of Purdue) until 2018, the Sacklers voted dozens of times to pay out Purdue’s opioid profits to their family—more than four billion dollars in total.

84. The following graph displays the yearly payouts the Sacklers voted to award themselves:



85. In order to enhance their own and Purdue’s social standing and prestige, the Sacklers endowed many cultural, educational and scientific institutions, many of which bear the family name, including Harvard University, Tufts University in Massachusetts, the New York Academy of Sciences, Columbia University, Dia Art Foundation, the Metropolitan Museum of Art,

the Solomon R. Guggenheim Museum, the Victoria and Albert Museum, and the Louvre. There is a Sackler gallery at the Princeton University Art Museum and Sackler museums at Harvard University and Peking University in Beijing. Many of the Sacklers and their relatives are prominent New York and international socialites.

86. Purdue's CEOs John Stewart (2007-2013), Mark Timney (2014-2017), and Craig Landau (2017 to the present) each directed Purdue's deception. Russell Gasdia carried out the misconduct as Vice President of Sales and Marketing at all pertinent times until June 2014. These individuals are collectively referred to as the "Purdue Officers." The Sacklers and the Purdue Officers are collectively referred to as the "Purdue Individuals."

87. The Purdue Individuals voted for and/or directed payments to doctors to promote Purdue's drugs.

88. The Purdue Individuals all actively participated in and benefited from Purdue's common law torts and statutory violations. This misconduct was not, and could not have been through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

89. In 2007, Purdue settled criminal and civil charges for misbranding OxyContin and agreed to pay the United States \$635 million – one of the largest settlements with a drug company for marketing misconduct. In the same year, Purdue settled with 27 states for its Consumer Protection Act violations regarding its extensive off-label marketing of OxyContin and its failure to adequately disclose abuse and diversion risks associated with the drug. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year. All of the Sacklers (except David) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive,

unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 has been knowing, purposeful, reckless, and intentional.

90. Purdue employed sales representatives in New York to promote Purdue's opioids in New York and sold millions of dollars of opioids in New York.

91. Purdue's misconduct caused tortious injury in New York by killing hundreds of people and injuring many more.

92. Collectively, Actavis, Amneal, Teva, Cephalon, Janssen, Endo, Abbott, Allergan, and Practice Fusion are referred to as "Marketing Defendants." Throughout this Complaint, Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt, although not named as defendants in this action, are included as participants in any conduct alleged of the "Marketing Defendants" as a collective entity and in any conduct alleged of "Defendants" as a collective entity.

## 2. Distributor Defendants

93. The Distributor Defendants are described below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and prevent diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with New York law, under which they are "distributors." Plaintiffs allege that the Distributor Defendants' unlawful conduct is a substantial cause of the volume of prescription opioids plaguing Plaintiffs' communities.

### a. AmerisourceBergen

94. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

95. AmerisourceBergen is a wholesaler of pharmaceutical drugs and distributes opioids throughout the country, including in New York. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016.

96. According to its 2016 annual report, AmerisourceBergen is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”<sup>16</sup>

**b. Anda**

97. Defendant Anda, Inc. (“Anda”) is a Florida corporation with its principal place of business in Weston, Florida.

98. Anda, through its various DEA-registered subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva Ltd. acquired Anda from Allergan plc (i.e., Actavis), for \$500 million in cash.

99. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in New York and within the communities served by Plaintiffs.

**c. Cardinal**

100. Defendant Cardinal Health, Inc. (“Cardinal”) is an Ohio corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of \$121.5 billion.

101. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. From 2006 to 2014, Cardinal was the second largest distributor of opioids in New York.

102. In December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States.

---

<sup>16</sup> AmerisourceBergen, 2016 Summary Annual Report, <http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d50108dbb>.

**d. H.D. Smith**

103. Defendant H.D. Smith, LLC f/k/a H.D. Smith Wholesale Drug Co. (“H.D. Smith”) through its various DEA-registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including in New York and the communities served by Plaintiffs. H.D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H.D. Smith Wholesale Drug Co. has been restructured and is currently doing business as H.D. Smith, LLC. H.D. Smith, LLC’s sole member is H.D. Smith Holdings, LLC, and its sole member is H.D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H.D. Smith is the largest independent wholesaler in the United States. In January 2018, Defendant AmerisourceBergen acquired H.D. Smith.

**e. Henry Schein**

104. Defendant Henry Schein, Inc. (“Henry Schein”) is incorporated in Delaware with its principal place of business located in Melville, New York.

105. Henry Schein describes its business as providing products and services to integrated health systems in the non-acute care space and distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, office-based medical practitioners, and ambulatory surgery centers. Overall, it is the world’s largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

106. At all relevant times, Henry Schein was in the business of distributing and redistributing pharmaceutical products, including opioids, to customers within the State of New York.

107. In 2015, Henry Schein reported that its sales reached a record \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995.

108. Cardinal, Anda, H.D. Smith, Henry Schein, and AmerisourceBergen are collectively

referred to as the “Distributor Defendants.”

### 3. National Retail Pharmacies

#### a. CVS

109. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island. CVS Pharmacy, Inc. held a license to distribute pharmaceuticals into New York from a distribution center located in Lumberton, New Jersey from March 19, 2007 to June 15, 2017. On information and belief, it used this license to distribute prescription opioids to CVS stores in New York during that time.

110. Defendant CVS Indiana, L.L.C. is an Indiana limited liability company that held a license to distribute pharmaceuticals in New York from January 11, 2010 to June 15, 2017. On information and belief, it used this license to distribute prescription opioids to CVS stores in New York during that time.

111. Defendant CVS Orlando FL Distribution, L.L.C. is a Florida limited liability company. Its sole member is Defendant CVS Pharmacy, Inc. It held a license to distribute pharmaceuticals in New York from July 23, 2012 until June 15, 2017. On information and belief, it used this license to distribute prescription opioids to CVS stores in New York.

112. Defendant CVS PA Distribution, L.L.C. is a Pennsylvania limited liability company that held a license to distribute pharmaceuticals into New York from June 10, 2009 to June 15, 2017. On information and belief, it used this license to distribute prescription opioids to CVS stores in New York.

113. Defendant CVS TN Distribution, L.L.C. is a Tennessee limited liability company. Its sole member is Defendant CVS Pharmacy, Inc. It held a license to distribute pharmaceuticals in New York from June 14, 2012 to June 15, 2017. On information and belief, it used that license to distribute prescription opioids to CVS stores in New York during that time.

114. Defendant CVS Vero FL Distribution, L.L.C. is a Florida limited liability company. It held a license to distribute pharmaceuticals in New York from July 25, 2012 to June 15, 2017. On



information and belief, it used this license to distribute prescription opioids to CVS stores in New York during that time.

115. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Rhode Island. Doing business as CVS Pharmacy Distribution Center and as Retail Pharmacy Customer Care Center it has held licenses to distribute pharmaceuticals into New York since March 29, 2011 and January 26, 2011, respectively. On information and belief, it has used these licenses to distribute prescription opioids to CVS stores in New York during this time.

116. Defendant CVS Albany, L.L.C. is a New York limited liability company with its principal place of business in Rhode Island. It operates CVS stores throughout New York and holds numerous licenses to dispense pharmaceuticals through those stores. It has used these licenses to dispense prescription opioids.

117. CVS Pharmacy, Inc.; CVS Indiana, L.L.C.; CVS Orlando FL Distribution, L.L.C.; CVS PA Distribution, L.L.C.; CVS TN Distribution, L.L.C.; CVS Vero FL Distribution, L.L.C.; CVS Rx Services, Inc.; CVS Albany, L.L.C. are collectively referred to as "CVS."

118. At all times relevant to this Complaint, CVS distributed and dispensed prescription opioids throughout the United States, including in New York.

#### **b. Rite-Aid**

119. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid of Maryland has held a license to distribute pharmaceuticals into New York since May 1, 2003. On information and belief, it used this license to distribute prescription opioids to Rite Aid stores in New York during this time.

120. Defendant Rite Aid of New York, Inc. is a New York corporation with its principal place of business in Camp Hill, Pennsylvania. It held and continues to hold licenses to dispense pharmaceuticals from Rite Aid stores in New York. It has used these licenses to dispense prescription opioids from Rite Aid stores in New York.

121. Defendant Rite Aid Drug Palace, Inc. is a Delaware Corporation with its principal place of business in Camp Hill, Pennsylvania. It held and continues to hold licenses to dispense pharmaceuticals from Rite Aid stores in New York. It has used these licenses to dispense prescription opioids from Rite Aid stores in New York.

122. Rite Aid of Maryland, Inc.; Rite Aid of New York, Inc.; and Rite Aid Drug Palace, Inc. are collectively referred to as "Rite Aid."

123. At all times relevant to this Complaint, Rite Aid distributed and dispensed prescription opioids throughout the United States, including in New York.

124. In 2018, Rite Aid sold many of its stores in New York and the licenses to dispense pharmaceuticals were transferred to other entities not affiliated with Rite Aid. However, Rite Aid continue to operate many pharmacies in New York that dispense prescription opioids.

#### c. Walgreens

125. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. has held a license to distribute pharmaceuticals into New York since August 24, 2005. On information and belief, it has used this license to distribute prescription opioids to Walgreens stores in New York during this time.

126. Walgreen Co. operates a distribution center in Mount Vernon, Illinois that has held a license to distribute pharmaceuticals into New York since November 3, 2014. On information and belief, it has used this license to distribute prescription opioids to Walgreens stores in New York during this time.

127. Defendant Walgreen Eastern Co., Inc. ("WEC") is a New York corporation with its principal place of business in Deerfield, Illinois. WEC held and continues to hold licenses to dispense pharmaceuticals from numerous Walgreens stores in New York. It uses and has used these licenses to dispense prescriptions opioids from those stores.

128. Walgreen Co. and WEC are collectively referred to herein as "Walgreens."

129. At all times relevant to this Complaint, Walgreens distributed and dispensed

prescription opioids throughout the United States, including in New York.

**d. Walmart**

130. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business in Arkansas.

131. Defendant, Wal-Mart Stores East, L.P. is a Delaware limited partnership with its principal place of business in Arkansas. Wal-Mart Stores East, L.P. holds a number of licenses to dispense pharmaceuticals from Walmart stores in New York. It has used these licenses to dispense prescriptions opioids from those stores.

132. Walmart, Inc. and Wal-Mart Stores East, L.P. are collectively referred to as “Walmart.”

133. At all times relevant to this Complaint, Walmart distributed and dispensed prescription opioids throughout the United States, including in New York.

134. Walmart operates a distribution center in Williamsport, Maryland (Wal-Mart Warehouse #46) that has held a license to distribute pharmaceuticals into New York since March 24, 2003 and a distribution center in Rogers, Arkansas (Wal-Mart Pharmacy Warehouse #45) that held a license to distribute pharmaceuticals into New York from May 8, 2003 until June 11, 2019. On information and belief, it has used these licenses to distribute prescription opioids to Walmart stores in New York.

135. Collectively, Defendants CVS, Rite Aid, Walgreens, and Walmart are referred to as the “National Retail Pharmacies.”

136. The Distributor Defendants and the National Retail Pharmacies are collectively referred to as the “Supply Chain Defendants.”

**4. Defendants’ Agents and Affiliated Persons**

137. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

138. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

139. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors, and/or their alter egos, sued herein as Does 1 through 100 inclusive, are presently unknown to Plaintiffs, who therefore sue these Defendants by fictitious names. Plaintiffs will seek leave of this Court to amend this Complaint to show their true names and capacities when they become ascertained. Each of the Doe Defendants has taken part in and participated with and/or aided and abetted some or all of the other Defendants in some or all of the matters referred to herein and therefore are liable for the same.

#### **IV. THE HARM CAUSED BY DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF THEIR LEGAL DUTIES**

140. As the Marketing Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products—and the rates of opioid-related substance abuse, hospitalization, and death among the people of New York. The Supply Chain Defendants have continued to unlawfully ship and dispense these massive quantities of opioids.

141. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”<sup>17</sup>

142. Opioid analgesics are widely diverted and improperly used, and the widespread use of these drugs has resulted in a national epidemic of opioid overdose deaths and addictions.<sup>18</sup>

<sup>17</sup> See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), <http://www.nejm.org/doi/full/10.1056/NEJMs1406143>.

<sup>18</sup> See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

143. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”<sup>19</sup>

144. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.<sup>20</sup>

145. For example, one doctor in Ohio was convicted of illegally distributing some 30,000 tablets of oxycodone, OxyContin, and Opana. In connection with sentencing, the U.S. Attorney explained: “Our region is awash in opioids that have brought heartbreak and suffering to countless families.” Henry Schein delivered opioids directly to the office of this doctor, whom the Northern District of Ohio described as “selling 30,000 doses of poison into the community.”<sup>21</sup> In a separate civil suit, the same prescriber reached a consent judgment alleging that he was purchasing hydrocodone/APAP tablets (hydrocodone and acetaminophen) from Henry Schein on as many as fourteen separate dates within a one-year period, and, subsequently dispensed 11,500 hydrocodone tablets without maintaining required purchasing and dispensing records.

146. The opioid epidemic poses an ongoing public health crisis in New York State. Each day, about nine people living in New York die as a result of opioid-related overdoses. Between 2009 and 2015, the number of deaths across the state resulting from prescription opioids alone nearly doubled.<sup>22</sup> <sup>23</sup> There was a 200 percent increase in the number of opioid overdose deaths between 2010 and 2017.<sup>24</sup>

<sup>19</sup> See Robert M. Califf, et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480 (2016) (hereinafter, “*A Proactive Response*”).

<sup>20</sup> See *Prescription Painkiller Overdoses in the U.S.*, CDC Vital Signs (Nov. 2011), <https://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html>.

<sup>21</sup> Eric Heisig, *Former Akron Area Doctor Sentenced to 63 Months in Prison for Dozing Out Painkillers*, Cleveland.com (Mar. 16, 2015), <https://www.cleveland.com/court-justice/index.ssf/2015/03/former-akron-area-doctor-sente.html>.

<sup>22</sup> New York State Department of Health, *Opioid Poisoning, Overdose and Prevention: 2015 Report to the Governor and NYS Legislature*, <https://www.health.ny.gov/diseases/aids/general/opioid-overdose-prevention/docs/annual-report2015.pdf>.

<sup>23</sup> New York State Department of Health, *New York State Opioid Annual Report 2017*, <https://www.health.ny.gov/statistics/opioid-data/pdf/nys-opioid-annual-report-2017.pdf>.

<sup>24</sup> New York State Department of Health, *New York State Opioid Annual Report 2019*, <https://www.health.ny.gov/statistics/opioid-data/pdf/nys-opioid-annual-report-2019.pdf>.

147. The opioid epidemic is fueled by both lawful and illegally obtained opioids. Nearly 9 million opioid prescriptions were dispensed in New York in 2015.<sup>25</sup> In 2018, there were 34 opioid prescriptions written for every 100 persons.<sup>26</sup> Between 2010 to 2017, increases in deaths involving synthetic opioids (other than methadone), primarily fentanyl, drove most of the increase in deaths. In 2017, there were 3,224 overdose deaths, of which 1,044 involved commonly prescribed opioids, 1,356 involved heroin, and 2,238 involved synthetic opioids (other than methadone).<sup>27</sup>

148. Opioid abuse has reached epidemic levels in New York. Between 2011 and 2014, approximately 145,000 New Yorkers annually abused or were dependent on opioids.<sup>28</sup>

149. Opioid misuse continues to have a large impact on treatment and hospitalizations in this state. Among New York residents, the number of hospital discharges for opioid use (including overdose, abuse, dependence, and unspecified use) increased from 25,089 in 2016 to 25,567 in 2017, and crude rate per 100,000 population increased from 127.7 to 130.5.<sup>29</sup> In 2017, there were 12,378 visits to emergency departments due to an opioid overdose among New York residents, an 11 percent increase from 2016.<sup>30</sup>

150. Recently disclosed data from the DEA's confidential Automation of Reports and Consolidated Orders System (ARCOS) shows the magnitude of opioid distribution throughout New York State.

151. There were 30,298,710 prescription pain pills supplied to Cattaraugus County from 2006 to 2014. That is enough pills for 41 pills per person per year. Amneal Pharmaceuticals manufactured 2,049,700 of those pills, and CVS distributed 2,599,400 of those pills.

<sup>25</sup> New York State Department of Health, "Opioid-related Data in New York State," <https://www.health.ny.gov/statistics/opioid/>

<sup>26</sup> <https://www.cdc.gov/drugoverdose/maps/rxstate2018.html>.

<sup>27</sup> New York State Department of Health, *New York State Opioid Annual Report 2019*, [https://www.health.ny.gov/statistics/opioid/data/pdf/nys\\_opioid\\_annual\\_report\\_2019.pdf](https://www.health.ny.gov/statistics/opioid/data/pdf/nys_opioid_annual_report_2019.pdf)

<sup>28</sup> NYSHHealth Foundation, *Targeting An Epidemic: Opioid Prescribing Patterns By County In New York State*, (December, 2017), available at <https://nyshealthfoundation.org/wp-content/uploads/2017/12/targeting-opioid-epidemic-new-york-state-dec-2017.pdf>

<sup>29</sup> New York State Department of Health, *New York State Opioid Annual Report 2019*, [https://www.health.ny.gov/statistics/opioid/data/pdf/nys\\_opioid\\_annual\\_report\\_2019.pdf](https://www.health.ny.gov/statistics/opioid/data/pdf/nys_opioid_annual_report_2019.pdf)

<sup>30</sup> *Id.*

152. There were 395,181,888 prescription pain pills supplied to Erie County from 2006 to 2014. That is enough pills for 47 person per year. Amneal Pharmaceuticals manufactured 14,654,500 of those pills, and Walgreens distributed and dispensed 47,803,020 of those pills.

153. There were 97,256,375 prescription pain pills supplied to Niagara County from 2006 to 2014. That is enough pills for 50 pills per person per year. Actavis Pharma, Inc. manufactured 24,845,995 of those pills, and Rite Aid distributed 7,801,500 of those pills.

154. There were 36,209,610 prescription pain pills supplied to Schenectady County from 2006 to 2014. That is enough pills for 26 pills per person per year. Actavis Pharma, Inc. manufactured 5,028,300 of those pills, and Wal-Mart distributed 2,557,400 of those pills.

155. New York's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs. Opioid prescriptions rose ninefold between 2000 and 2011.<sup>31</sup> Opioid-related overdose fatalities have more than doubled since 2013.<sup>32</sup> Deaths in which prescription opioids were a contributing factor reached a new peak in 2014, nearly four times the level in 2005. Comparing the death rate in 2005 and 2014 for prescription opioids, New York's increased more than almost any other state for which such data were available.<sup>33</sup>

156. Between 2013 and 2015, drug manufacturers spent more than \$3.5 million in opioid promotion activities with thousands of New York State physicians. Roughly 1 in 10 physicians who prescribed opioids received a payment, and physicians who prescribed more opioids got more opioid-related payments.<sup>34</sup>

---

<sup>31</sup> ARCOS Retail Drug Summary Reports, Drug Enforcement Admin. Diversion Control Div., [https://www.deadiversion.usdoj.gov/arcos/retail\\_drug\\_summary](https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary); Population and Housing Unit Estimates, U.S. Census Bureau, <https://www.census.gov/programs-surveys/popest.html>.

<sup>32</sup> Cody Colon-Berezin et al., *Overdose Deaths Involving Fentanyl and Fentanyl Analogs — New York City, 2000–2017*, 68 Morbidity & Mortality Wkly. Rep. 37–40 (Jan. 18, 2019), available at, <https://www.cdc.gov/mmwr/volumes/68/wr/mm6802a3.htm>.

<sup>33</sup> Office of the N.Y. State Comptroller, Prescription Opioid Abuse and Heroin Addiction in New York State 1–2 (June 2016), available at [https://www.osc.state.ny.us/press/releases/june16/heroin\\_and\\_opioids.pdf](https://www.osc.state.ny.us/press/releases/june16/heroin_and_opioids.pdf).

<sup>34</sup> NYSHHealth Foundation, *Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State*, (June, 2018), available at <https://nyshealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf>.

157. The progression from prescription opioids to the use of illicit drugs, particularly injectable heroin, is well documented; approximately 75% of heroin users report that their initial drug use was through prescription opioids.<sup>35</sup> As New York citizens who become addicted to prescription opioids have predictably migrated to less expensive illicit opioids, namely heroin and fentanyl, overdoses have dramatically increased. In New York State, rates of overdose death involving commonly prescribed opioids increased from 3.7 per 100,000 in 2010 to 5.1 in 2017. There has not been a simultaneous increase in the fentanyl prescribing rates, indicating this increase is driven primarily by illicitly manufactured fentanyl.<sup>36</sup>

158. Opioids have endangered public health in New York even beyond addiction and overdose. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs (a substantial portion of which were paid by Plaintiffs), increased costs and burdens imposed on the criminal justice system, and costs associated with the lost productivity of addicts.<sup>37</sup> Recognizing these costs, New York Attorney General Letitia James has brought a complaint against the manufacturers, distributors, and individuals who engaged in deceptive marketing practices about the dangers of opioids and egregiously breached their duties to avoid unlawful diversion of opioids.<sup>38</sup> The Attorney General's complaint alleges that the defendants are largely responsible for creating the opioid epidemic that has ravaged New York, causing widespread addiction, overdose deaths, and suffering.<sup>39</sup>

159. Children have been especially vulnerable to the opioid epidemic. Along with overdose

---

<sup>35</sup> Theodore J. Cicero, et al., *The Changing Face of Heroin Use in The United States: A Retrospective Analysis of The Past 50 Years*, JAMA Psychiatry (2014); 71(7):821-826, <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

<sup>36</sup> New York State Department of Health, *New York State Opioid Annual Report 2019*, [https://www.health.ny.gov/statistics/opioid\\_data/pdf/nys\\_opioid\\_annual\\_report\\_2019.pdf](https://www.health.ny.gov/statistics/opioid_data/pdf/nys_opioid_annual_report_2019.pdf)

<sup>37</sup> Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, Am. Enter. Inst. (Mar. 20, 2018), available at <https://www.aei.org/wp-content/uploads/2018/03/Geographic-Variation-in-Cost-of-Opioid-Crisis.pdf>.

<sup>38</sup> <https://ag.ny.gov/press-release-2019-attorney-general-james-files-nations-most-comprehensive-suit-against-opioid>

<sup>39</sup> *Id.*



deaths, the rate of neonatal abstinence syndrome (“NAS”) – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in New York. New York experienced 14.7 cases for every 1000 hospital births in 2017.<sup>40</sup> Between 2010 and 2014, the incidence of NAS in New York State has increased 79%, from a rate of 2.9 cases per 1,000 live births in 2010 to 5.2 cases per 1,000 live births in 2014. The rate of opioid overdose deaths for females of reproductive age, 18 to 44 years old, has tripled in NYS, from 4.2 per 100,000 in 2010, to 12.7 per 100,000 in 2016.<sup>41</sup>

160. On average, a child suffering from NAS will stay in the hospital nearly 3.5 times as long as a child without NAS.<sup>42</sup> The average treatment cost for a child suffering from NAS is over three times that of a child who does not have NAS.<sup>43</sup> Infants with a NAS-related diagnoses are more likely to have respiratory disorders, low birth weight, and seizures.<sup>44</sup> These infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs – a process so painful that it traps many adults on opioids. When untreated, NAS can be life-threatening. Children are also injured by the removal from their homes due to opioid abuse and addiction.

161. New York State has also seen an increase in blood-borne infections caused by intravenous drug use, including hepatitis C and the human immunodeficiency virus (HIV). In 2017, 8% of new HIV cases in males and 13.5% in females were attributed to intravenous use of opioids.<sup>45</sup> Nationally, 86.6% of new hepatitis C cases are attributed to intravenous drug use. Hepatitis C can ultimately cause liver cancer, fibrosis, or cirrhosis and is the leading cause of liver transplants.

162. Across New York State, families and communities face heartbreaking tragedies that

---

<sup>40</sup><https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/new-york/opioid-involved-deaths-related-harms>.

<sup>41</sup> Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2016 on CDC WONDER Online Database, released December, 2017. Accessed at <http://wonder.cdc.gov/mcdicd10.html>

<sup>42</sup> Tammy E. Corr & Christopher S. Hollenbeak, *The economic burden of neonatal abstinence syndrome in the United States*, 2017 Sep;112(9):1590-1599, <https://pubmed.ncbi.nlm.nih.gov/28612362/>.

<sup>43</sup> *Id.*

<sup>44</sup> S.W. Patrick, et al., *Risk of Hospital Readmission Among Infants With Neonatal Abstinence Syndrome*, *Hospital Pediatrics*, 5(10), 513–519, <https://doi.org/10.1542/hpeds.2015-0024>.

<sup>45</sup><https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/new-york/opioid-involved-deaths-related-harms>.

cannot be adequately conveyed by statistics, and they have faced them all too often. Many grieving families have been financially tapped out by the costs of repeated cycles of addiction treatment programs; other have lost hope and given up. The increasing number of cases takes both a physical and mental toll on investigators, first-responders, and hospitals such as Plaintiffs.

163. Reflecting New York State's public policy response to the opioid epidemic, the state has enacted laws and regulations to further reduce overprescribing of opioid medications. Effective July 22, 2016, initial opioid prescribing for acute pain is limited to a 7-day supply. N.Y. Pub. Health Law § 3331(5)(a). Long-term opioid treatment requires that the prescriber institute a written treatment plan that follows generally accepted national professional or governmental guidelines. *Id.* § 3331(8).

164. New York State physicians and other individuals authorized to prescribe opioids by the DEA must complete mandatory three hours of coursework on pain management, palliative care, and addiction every three years.<sup>46</sup>

165. Similarly, the legislature has authorized the establishment of a "prescription pain medication awareness program to educate the public and health care practitioners about the risks associated with prescribing and taking controlled substance pain medications." N.Y. Pub. Health Law § 3309-a.

166. As shown above, the opioid epidemic has escalated with devastating effects: opiate-related substance abuse, hospitalization, misery, social decay, and death that goes hand in hand with Defendants' increased distribution of opioids.

167. Defendants repeatedly and purposefully breached their duties under the law, and such breaches are direct and proximate causes of and/or substantial factors leading to the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals such as Plaintiffs.

---

<sup>46</sup> [https://www.health.ny.gov/professionals/narcotic\\_laws\\_and\\_regulations/](https://www.health.ny.gov/professionals/narcotic_laws_and_regulations/)

### **A. Impact of Opioids on New York Hospitals**

168. Hospitals—legally and morally—are compelled to treat patients with opioid-related conditions<sup>47</sup> and, as a result, have been directly and monetarily damaged by the opioid epidemic. In addition to the cost of the opioid drugs themselves, hospitals have incurred and continue to incur millions of dollars in damages for the costs of care as a result of the unlawful marketing, distribution, and sale of opioids. Arguably, more than any other institution, hospitals directly and monetarily bear the brunt of the opioid crisis.

169. These costs do not arise merely from patients who do not pay their bills. Instead, the financing mechanisms of modern healthcare set particular rates for particular types of treatment. If treatment becomes more complicated or expensive (as it does in patients with opioid dependency or addiction as a comorbidity), then a healthcare provider's rate of realization declines. For example, it is increasingly common for individuals addicted to opioids to present at a hospital with endocarditis, treatment for which may involve surgery followed by intravenous antibiotic treatment. This treatment requires installation of an IV port in the patient; typically, a patient with such a port will be released and will receive their intravenous antibiotics on an outpatient basis. However, because IV ports provide a ready route for intravenous drug use, the standard of care for patients with IV ports who have a concurrent opioid use disorder is to conduct the entire course of treatment on an inpatient basis. The extra costs of providing extended inpatient care to individuals with opioid use disorders lowers and, in some cases, eliminates the profit that a hospital realizes from the rate of payment the hospital has negotiated with insurers and other payors.

170. Because of Defendants' conduct, the opioid epidemic is placing an increasing strain on New York's overburdened health care system.

---

<sup>47</sup> "Opioid-related conditions" include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis-C, and HIV; surgical procedures that are more complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs' records as related to opioid use and abuse.

171. Defendants' misrepresentations, along with those of the Front Groups and the KOLs, prompted New York health care providers to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying an extravagant quantity of into New York communities, so much that the only logical conclusion was that the product was being diverted and used illicitly.

172. During admission, hospital professionals routinely consult with patients to assess which medications the patients are taking at home. Due to Defendants' conduct, hospitals can no longer trust patients to self-report their prescriptions. Hospital pharmacists may also check available databases to ensure that patients are not stockpiling prescription opioids, but such databases often do not record the actual flow of opioids. Hospital pharmacies' inability to rely on their patients' self-reporting and having to take additional steps to independently verify their patients' purchases from other sources impose additional burdens on hospitals.

173. Hospitals must treat opioid users who present in need of emergency care. Defendants knew that hospitals were required to treat opioid-addicted patients. In 2011, it is "estimated that [there were] greater than 420[,000 emergency room] visits related to the misuse of abuse of narcotic pain relievers" in the United States.<sup>48</sup>

174. Similarly, if a pregnant opioid addict presents for treatment, the hospital must provide care for both the opioid-addicted mother and the opioid-addicted baby. Defendants relied on Plaintiffs to mitigate the health consequences of Defendants' illegal activities by providing a safety net to prevent overdose deaths and treat the health consequences arising from opioid addiction.<sup>49</sup>

---

<sup>48</sup> Cindy Williams, Vice President and Chief Pharmacy Officer, Riverside Health System, *Establishment of an Opioid Stewardship Program*, [http://www.rshp.org/uploads/63606360223\\_williams-opioid\\_1\\_per\\_page.pdf](http://www.rshp.org/uploads/63606360223_williams-opioid_1_per_page.pdf).

<sup>49</sup> Cheryl Genord, et al., *Opioid exit plan: A pharmacist's role in managing acute postoperative pain*, *Journal of the American Pharmacists Association* (Jan. 2017), [https://www.japha.org/article/S1544-3191\(17\)30016-X/fulltext](https://www.japha.org/article/S1544-3191(17)30016-X/fulltext) (hereinafter "*Opioid Exit Plan*").

175. The unlawful diversion of prescription opioids is a direct and proximate cause of and/or substantial factor leading to prescription opioid abuse, addiction, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

176. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

**B. Impact of Defendants' Activities on Plaintiffs**

177. Plaintiffs operate hospitals located throughout New York. The service areas of Plaintiffs' hospitals have been hit hard by the opioid crisis.

178. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) hepatitis C, HIV, and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in its NICU for babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy and highly expensive; and (5) psychiatric and related treatment for patients with opioid addiction who present in need of mental health treatment programs.

179. Plaintiffs have incurred and continue to incur substantial costs to treat patients with opioid-related conditions. First, patients with opioid-related conditions seek treatment from Plaintiffs as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiffs' monetary losses with respect to treatment of these patients were and are foreseeable to Defendants and were and are the proximate result of Defendants' acts and omissions specified herein. Second, patients with opioid conditions have caused Plaintiffs to incur, and continue to incur, increased costs in the form of surgical procedures and other care that have been and are more complex and expensive than they would otherwise be if the patients were not using or abusing opioids.

180. Hospitals obtain a lower rate of realization (receipt of revenues as a percentage of billings for services provided) for care provided to patients in the prescription opioid cohort (patients who have historically and/or presently used prescription opioids) than for care provided to patients who do not have a history of prescription opioid use.

181. Additionally, individuals with opioid addiction have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to obtain opioids. Plaintiffs have incurred and continue to incur operational costs related to the time and expense of diagnosing, testing, and otherwise attempting to treat these individuals.

182. The costs incurred by Plaintiffs are the direct and proximate result of the marketing, distribution, and dispensing illegalities described above and the opioid epidemic created and engineered by Defendants. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increased use of opioids would result in a corresponding increase in patients with opioid-related conditions presenting for treatment at hospitals, including Plaintiffs. It was foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic because hospitals are on the front line of treatment for these patients and must bear the additional costs of that treatment.

183. The increased financial burdens on hospitals include, but are not limited to, the following:

- a. Financial impact of the increased costs of providing medical care to patients suffering from opioid-related addiction or disease as the reason for presentation for care and/or as a comorbidity;
- b. Financial impact of the increased costs associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients' self-reporting, it necessitates that further steps be taken in all phases of treatment and counseling;
- c. Financial impact of the costs of opioids purchased by hospitals themselves, which were direct targets of Defendants' marketing campaigns;
- d. Financial impact of the costs of prescription drugs used to treat addiction;
- e. Financial impact of the costs of training personnel in the proper treatment of drug overdoses;

- f. Financial impact of the costs associated with training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- g. Financial impact of the increased costs for providing mental-health, treatment, rehabilitation, and social services, s to victims of the opioid epidemic and their families;
- h. Financial impact of the costs treating infants born with opioid-related medical conditions or born dependent on opioids due to drug use by mothers during pregnancy;
- i. Financial impact of the cost of providing additional personnel to respond to security concerns created by patients and others suffering from opioid abuse and dependency;
- j. Financial impact of the costs of providing special programs over and above ordinary hospital services; and
- k. Financial impact of the costs of providing services to abate the nuisance created by Defendants' conduct for which Defendants are responsible and for which Plaintiffs have not been reimbursed.

184. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence. They do not seek to recover for damages which may have been suffered by individual citizens for wrongful death, physical injury, emotional distress, or any physical damage to property.

185. Plaintiffs do seek to recover the costs of abating the nuisance Defendants created by flooding their communities with opioids. Defendants are responsible for creating this nuisance and are responsible for abating it.

186. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected costs of a hospital's existence. Plaintiffs allege wrongful acts that were neither discrete nor of the sort a hospital can reasonably expect.

**V. THE MARKETING DEFENDANTS' AND CVS'S FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS**

187. The opioid epidemic was no accident.

188. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, for pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors did not generally prescribe opioids for chronic pain.

189. Each Marketing Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating their benefits as treatment for chronic pain.

190. The Marketing Defendants have disseminated these common messages to reverse the generally accepted medical understanding of opioids and their risks. They disseminated these messages through their sales representatives, including the Sales Representative Defendants, through speaker groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

191. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion annually since 2009.<sup>51</sup>

---

<sup>51</sup> See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE, Nov. 9, 2011, <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, FINANCIAL TIMES, Aug. 10, 2016, <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95>.



192. In an open letter to the nation's physicians in August 2016, the U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."<sup>51</sup> This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

193. The Marketing Defendants intentionally continued their conduct knowing that it was creating the opioid nuisance and causing the harms and damages alleged herein.

194. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance. The harm to public health, safety, and environment created by this public nuisance is ongoing and has not been abated.

195. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of harm prevented by, *inter alia*, (a) preventing the next cycle of addiction by educating patients and prescribers (especially primary care physicians and the most prolific prescribers of opioids) about the true risks and benefits of opioids, including the risk of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

196. Defendants have the ability to act to abate the public nuisance, and the law requires that they do so. The manufacturer of a drug has primary responsibility to ensure the safety, efficacy, and appropriateness of its labeling, marketing, and promotion. All companies in the supply chain of a controlled substance are responsible for ensuring that the drugs are only distributed and dispensed to appropriate patients and not diverted. The responsibility to ensure that their products and practices

---

<sup>51</sup> Letter from Vivek H. Murthy, M.D., U.S. Surgeon General (Aug. 2016), <http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf>.

meet state controlled substances and consumer protection laws and regulations is independent of any FDA or DEA regulation. As registered manufacturers, distributors, and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

197. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States, including in New York. The Marketing Defendants also deployed seemingly unbiased and independent third parties to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

198. Across the pharmaceutical industry, “core message” development is overseen on a national basis from drug manufacturers’ corporate headquarters. This comprehensive approach ensured that the Marketing Defendants’ messages are accurately and consistently delivered across marketing channels – including prescriber visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants considered this high level of coordination and uniformity crucial to successfully marketing their drugs.

199. The Marketing Defendants ensured nationwide consistency through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants’ sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors periodically rode along with them to check on their performance and compliance.

**A. The Marketing Defendants’ False and Deceptive Statements About Opioids.**

200. The Marketing Defendants’ misrepresentations fall into the following ten categories:

- a. The risk of addiction from chronic opioid therapy is low;
- b. To the extent there is a risk of addiction, it can be easily identified and

- managed;
- c. Signs of addictive behavior are “pseudoaddiction,” requiring more opioids;
  - d. Addicted patients are “untrustworthy” “abusers;”
  - e. Opioid withdrawal can be avoided by tapering;
  - f. Opioid doses can be increased without limit or increased risk;
  - g. Long-term opioid use improves functioning;
  - h. Alternative forms of pain relief pose greater risks than opioids;
  - i. A version of oxycodone marketed by Purdue provides 12-hour pain relief; and
  - j. New formulations of certain opioids successfully deter abuse.

201. Each of these propositions was false. The Marketing Defendants knew this, but nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

202. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort—not as a checklist for assessing each Marketing Defendant’s liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant’s conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant’s misrepresentations and the manner in which they were disseminated, they are just that—examples. This Complaint is not, especially prior to discovery, an exhaustive catalog every deceptive statement by each Marketing Defendant.

**1. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low.**

203. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

204. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support that claim. None of them have acknowledged, retracted, or corrected their false statements.

205. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose;"<sup>52</sup> the risk substantially increases with more than three months of use.<sup>53</sup> As the CDC Guideline states, "Opioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).<sup>54</sup>

**a. Purdue and Abbott's Misrepresentations Regarding Addiction Risk**

206. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Marketing Defendants) found this

---

<sup>52</sup> FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

<sup>53</sup> Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, 65(1) Morbidity and Mortality Weekly Report (Mar. 2016), at 21, available at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf> (hereinafter "Dowell, CDC Guideline").

<sup>54</sup> *Id.* at 2.

“research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (“NEJM”) in 1980.

207. This letter, by Jane Porter and Dr. Hershel Jick, declared the incidence of addiction “rare” for patients treated with opioids.<sup>55</sup> They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

208. The brevity of this letter is apparent at a glance:

#### ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

*To the Editor:* Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients<sup>1</sup> who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,<sup>2</sup> Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER  
HERSHEL JICK, M.D.  
Boston Collaborative Drug  
Surveillance Program

Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

---

<sup>55</sup> Jane Porter & Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221> (hereinafter “Porter & Jick Letter”).

209. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.<sup>56</sup>

210. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.<sup>57</sup> Citation to the letter, which had been largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, according to Dr. Jick, “that’s not in any shape or form what we suggested in our letter.”

211. Purdue specifically used the Porter & Jick letter in a 1998 promotional video, “I got my life back,” in which Dr. Alan Spanos states, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*”<sup>58</sup> Purdue trained its sales representatives to tell prescribers that less than 1% of patients who took OxyContin became addicted. Purdue knew that this state was false because, in 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was 13%.<sup>59</sup>

212. Other Defendants relied on and disseminated the same false and deceptive messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the Porter & Jick letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of

---

<sup>56</sup> Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail Of Addiction And Death* 47 (2003) (herein after “*Pain Killer*”).

<sup>57</sup> Porter & Jick Letter, *supra*.

<sup>58</sup> Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI>, (last accessed August 1, 2018) (emphasis added).

<sup>59</sup> Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER, Oct. 30, 2017, <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> (hereinafter “*Empire of Pain*”).

addiction associated with long-term opioid therapy.”<sup>60</sup>

213. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”<sup>61</sup>

214. To complement the Porter & Jick letter, Purdue crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”<sup>62</sup>

215. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”<sup>63</sup>

216. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure, *A Guide to Your New Pain Medicine and How to Become a Partner Against Pain*. In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting?’” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

---

<sup>60</sup> Pamela T.M. Leung, et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N. Engl. J. Med. 2194-95 (June 1, 2017), DOI: 10.1056/NEJMc1700150 available at <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

<sup>61</sup> Marilyn Marchione, *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT NEWS (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

<sup>62</sup> Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996), <http://documents.latimes.com/oxycontin-press-release-1996>.

<sup>63</sup> *Oxycontin: Its Use and Abuse: Hearing Before the House Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg7554.html> CHRG-107hhrg7554.htm (hereinafter “*Oxycontin: Its Use and Abuse*”).

217. Sales representatives marketed OxyContin as a product “to start with and to stay with.”<sup>64</sup> Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”<sup>65</sup> According to the memo, the target is physician resistance: “The physician wants pain relief for these patients without addicting them to an opioid.”<sup>66</sup>

218. Purdue’s unbranded website, *Partners Against Pain*,<sup>67</sup> continued the lie: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.”

219. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that “it’s just too addictive.”<sup>68</sup> May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers that need to be taken every four hours.

---

<sup>64</sup> *Empire Of Pain*, *supra*.

<sup>65</sup> *Pain Killer*, *supra*, at 102.

<sup>66</sup> *Id.*

<sup>67</sup> *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

<sup>68</sup> David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), THE NEW YORKER (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.



220. According to interviews with prescribers and former Purdue sales representatives, Purdue has not only failed to correct its earlier misrepresentations, it has continued to distort or omit the risk of addiction, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

221. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

222. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

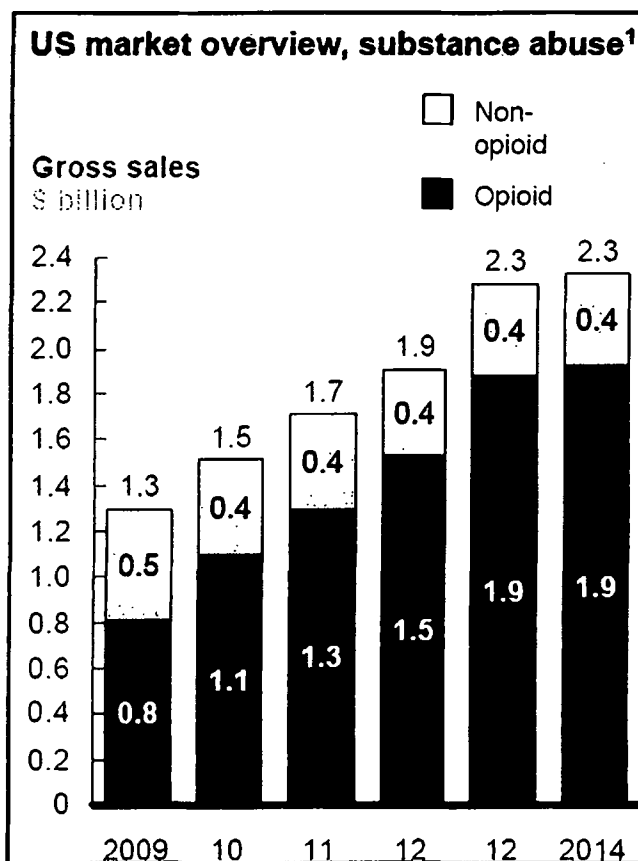
223. In 2001, Purdue revised the indication and warnings for OxyContin.

224. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy (or even the first opioid) used and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

225. Purdue's awareness of the addictive properties of their opioid products is best exemplified by its cynical attempts to profit from addiction treatment. In 2007, Richard Sackler filed an application for a patent for a purported treatment for opioid addiction. In September 2014, Kathe Sackler dialed in to a confidential call about *Project Tango* – a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In internal documents, Kathe and staff wrote down what Purdue had publicly denied for decades: addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a

picture of a dark hole labeled “Pain treatment” that a patient could fall into — and “Opioid addiction treatment” waiting at the bottom.

226. Nothing that “[o]pioid addiction (other than heroin) has grown by ~20% a [compound annual growth rate] from 2000 to 2010,” Ms. Sackler and the *Project Tango* team found that the “market” for opioid addiction treatment had more than doubled between 2009 to 2014, from \$0.8 billion to \$1.9 billion:



*Purdue's measure of the opioid addiction "market"*

227. Internal *Project Tango* documents also reveal that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. The truth, which Purdue knew, is that the real risk of addiction is not so limited:

- *"This can happen to any-one – from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury. from the very wealthy to the very poor"*

*Purdue's "Project Tango" patient and clinical rationale*

228. Kathe and the staff concluded that millions of people who became addicted to opioids were the Sacklers' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients hooked on opioids could now be used to sell treatment to get patients off them.

229. In June 2017, the Sacklers met to discuss a revised version of *Project Tango* - another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose antidote Narcan. The need for Narcan to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018.

**b. Endo's Misrepresentations Regarding Addiction Risk**

230. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

231. Until April 2012, Endo's website for Opana, [www.opana.com](http://www.opana.com), stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

232. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER.

233. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below.

234. APF conveyed through its National Initiative on Pain Control ("NIPC") and its website [www.Painknowledge.com](http://www.Painknowledge.com) that "[p]eople who take opioids as prescribed usually do not become addicted."

235. Another Endo website, *PainAction.com*, stated, “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

236. *Pain: Opioid Facts*, a brochure available on *Painknowledge.com*, stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

237. In a patient education pamphlet titled *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo answers the hypothetical patient question — “What should I know about opioids and addiction?” — by creating a false dichotomy between addiction (“a chronic brain disease”) and opioid therapy (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online and was edited by KOL Dr. Russell Portenoy.<sup>69</sup>

238. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on *Painknowledge.com*, omitted addiction from the “common risks” of opioids:

**As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following**

- Constipation
- Drowsiness
- Confusion
- Itching
- Nausea
- Vomiting
- Dizziness
- Difficulty breathing

Your healthcare provider will help you manage these side effects. Some side effects may occur as a result of opioid treatment. Some side effects may include drowsiness, constipation, confusion, itching, nausea, vomiting, dizziness, and difficulty breathing. If you experience any of these side effects, contact your healthcare provider immediately.

<sup>69</sup> Margo McCaffery, RN MS, FAAN & Chris Pasero, RN, MS FAAN, *Understanding Your Pain: Taking Oral Opioid Analgesics*, [http://www.thblack.com/links/rsd\\_understand\\_pain\\_opioid\\_analgesics.pdf](http://www.thblack.com/links/rsd_understand_pain_opioid_analgesics.pdf) (last accessed October 26, 2018).

**c. Mallinckrodt's Misrepresentations Regarding Addiction Risk**

239. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the C.A.R.E.S. Alliance.

240. In 2010, Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” C.A.R.E.S. Alliance is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.), copyrighted and registered as a trademark by Covidien, Mallinckrodt's former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose the link to Mallinckrodt.

241. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book entitled *Defeat Chronic Pain Now!* This book is still available online.<sup>70</sup> The false claims and misrepresentations in this book include the following:

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.” “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- c. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- d. “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who

---

<sup>70</sup> Bradley S. Galder & Charles Argoff, *Defeat Chronic Pain Now!: Groundbreaking Strategies for Eliminating the Pain of Arthritis, Back and Neck Conditions, Migraines, Diabetic Neuropathy, and Chronic Illness* (2010), [https://books.google.com/books?id=VcSQGYKXWdYC&printsec=frontcover&source=gbs\\_ViewAPI#v=snipper&q=only%20rarely%20does%20opioid%20medication&f=false](https://books.google.com/books?id=VcSQGYKXWdYC&printsec=frontcover&source=gbs_ViewAPI#v=snipper&q=only%20rarely%20does%20opioid%20medication&f=false).

does not have a prior history of addiction.”

- e. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics if (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- f. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

242. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated, “Sadly, even today, pain frequently remains undiagnosed and either untreated or undertreated,” and cited to a report that concludes, “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

243. Marketing Defendants’ suggestion that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme but is at odds with the facts. While there are patients who obtain opioids in order to abuse them, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

## **2. Falshood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed.**

244. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants asserted that to even if some patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires.

245. In materials they produced, sponsored, or controlled, Defendants instructed patients

and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

246. Purdue sponsored KOL Dr. Lynn Webster's 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

247. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques even high-risk patients showing signs of addiction could be treated with opioids.

248. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like the *Screening and Opioid Assessment for Patients with Pain* or the *Opioid Risk Tool*, which was created by Dr. Webster and linked to Janssen and to Endo-supported websites; and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

249. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such

screening can take opioids long-term without significant danger of addiction.

**3. Falsehood #3: Signs of Addictive Behavior are “Pseudoaddiction”  
Requiring More Opioids.**

250. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids.

251. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”<sup>71</sup> In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

252. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions and have never acknowledged, retracted, or corrected them.

253. In 2005, Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *Partners.AgainstPain.com*. It circulated the physical pamphlet through at least 2007 and posted it on its website through at least 2013. The pamphlet listed conduct, including “illicit drug use and deception,” that it claimed was not evidence of true addiction but rather “pseudoaddiction”:

A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may ‘clock watch,’ and may otherwise seem inappropriately ‘drug-seeking.’ Even such behaviors as illicit drug use and deception can occur in the patient’s efforts to obtain relief. Pseudoaddiction can be distinguished from true

---

<sup>71</sup> David E. Weissman & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>. (“Iatrogenic” describes a condition induced by medical treatment).



addiction in that the behaviors resolve when the pain is effectively treated.

254. According to documents provided by a former Purdue detailer (i.e., a sales representative), sales representatives were trained and tested on the meaning of pseudoaddiction, suggesting that they were directed to, and did, describe pseudoaddiction to prescribers.

255. A Purdue presentation for doctors titled *Medication Therapy Management* recited what had been the consensus view for decades: “Many medical students are taught that if opioids are prescribed in high doses or for a prolonged time, the patient will become an addict.” Purdue then assured doctors that this traditional concern about addiction was wrong and that such patients instead suffer from “pseudoaddiction” because “opioids are frequently prescribed in doses that are inadequate.” Doctors on Purdue’s payroll admitted in writing that pseudoaddiction was used to describe “behaviors that are clearly characterized as drug abuse” and put Purdue at risk of “ignoring” addiction and “sanctioning abuse.” But Purdue nevertheless urged doctors to respond to signs of addiction by prescribing higher doses of Purdue’s drugs.

256. In 2009, Endo sponsored a NIPC CME program, *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction. Endo also listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered when awarding grants to CME providers.

257. Endo has since repudiated the concept of pseudoaddiction. In finding that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”<sup>2</sup> Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

---

<sup>2</sup> Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc.*, Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 7, available at [https://www.ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf).

258. The FAQs section of *pain-topics.org*, a now-defunct website for which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to “keep in mind” that signs of potential drug diversion, rather than signaling “actual” addiction, “may represent pseudoaddiction,” which the website described as behavior that occurs in patients when pain is “undertreated” and includes patients becoming “very focused on obtaining opioid medications and may be erroneously perceived as ‘drug seeking.’”

259. The CDC Guideline nowhere recommends providing more opioids to patients exhibiting symptoms of addiction. Even Dr. Lynn Webster, a KOI, discussed below, has admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

#### **4. Falsehood #4: Addicted Patients are “Untrustworthy” “Abusers.”**

260. In 2001, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame people who become addicted to opioids. Sackler wrote in a confidential email: “we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.” The Sacklers chose to stigmatize people who were hurt by their opioids, calling them “junkies” and “criminals.”

261. In December 2011, John Stewart, Purdue CEO from 2007 to 2013, gave a speech titled *Providing Relief, Preventing Abuse*, which deceptively blamed addiction, overdose, and death on “abuse.”

262. Purdue managers praised sales representatives for pitching doctors on the idea that prescribing to “trustworthy” patients was safe. A sales rep reported that one doctor “let me know that she will Rx OxyContin when the pts [patients] has chronic pain and are trustworthy.” The rep added that he would “[f]ollow up with Dr and ask what pts does she consider ‘trust worthy?’” A Purdue district manager responded: “Great follow up question on what patients does he consider trustworthy.”

**5. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering.**

263. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient's dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

264. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.

265. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of further addiction.

266. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.

267. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

**6. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk.**

268. In materials they produced, sponsored, or controlled, the Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. The

Marketing Defendants' claims were deceptive because they omitted warnings (confirmed by scientific evidence) that more adverse effects occur at higher doses.

269. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. Because patients develop a tolerance to opioids' analgesic effects, achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses or who escalate to larger doses faster are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

270. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were not only more expensive, they also increased the likelihood of addiction.

271. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME (morphine milligram equivalents)/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. OxyContin tablets come in doses up to 108 mg of oxycodone.

272. In its 2010 Risk Evaluation and Mitigation Strategy for OxyContin, however, Purdue did not address the heightened risk of respiratory depression and death from increasing the dose and instead advised prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then

resume upward titration.”<sup>73</sup>

273. Endo sponsored a website, *Painknowledge.com*, which claimed that opioid doses may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

274. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response: “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

275. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A Veterans Health Administration study from 2004 to 2008 found the rate of overdose deaths to be directly related to the maximum daily dose.

#### **7. Falsehood #7: Long-term Opioid Use Improves Functioning.**

276. Despite the lack of evidence of improved function and the existence of contrary evidence, the Marketing Defendants consistently promoted opioids as a way to improve patients’ function and quality of life. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to counterbalance the known risks.

277. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the *Journal of the American Medical Association* (“*JAMA*”), proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson. By implying that OxyContin would help users’ function, this ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November

---

<sup>73</sup> Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/20101101000000/http://www.fda.gov/downloads/Drugs/DrugSafety/uc209901.pdf> (last modified Nov. 2010).

ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”<sup>4</sup>

278. Purdue sponsored APOF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support stated the contrary, noting the absence of long-term studies and concluding, “For functional outcomes, the other analgesics were significantly more effective than were opioids.”

279. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

280. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

281. Endo’s NIPC website, *Painknowledge.com*, claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

282. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

283. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he

---

<sup>4</sup> Chris Adams, *F.D.A Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL, (Jan. 23, 2003), <https://www.wsj.com/articles/SB1043259665976915824>.

effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”<sup>5</sup>

284. The Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and long-term functioning. For years, the FDA has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.<sup>6</sup> Based upon a review of the existing scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”<sup>7</sup>

285. Consistent with the CDC’s findings, substantial evidence exists that opioids are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . . .”<sup>8</sup> Evidence also shows that increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress

---

<sup>5</sup> Mallinckrodt Pharmaceuticals, *Responsible Use*, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use> (last accessed July 16, 2018) (hereinafter “*Responsible Use*”).

<sup>6</sup> See also Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <https://www.fda.gov/oc/ohrt/resources/files/archives/a/ActavisElizabethLLC.pdf> (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Defendants on the FDA website.

<sup>7</sup> Dowell, CDC Guideline, *supra*, at 20.

<sup>8</sup> Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med., at 1503 (Apr. 21, 2016), DOI: 10.1056/NEJMp1515917, available at <https://www.nejm.org/doi/full/10.1056/NEJMp1515917> (hereinafter “*Reducing the Risks of Relief*”).



disorder, and substance abuse), increased psychological distress, and greater health care utilization.

286. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”<sup>79</sup> According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”<sup>80</sup>

287. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”<sup>81</sup> In fact, research has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.<sup>82</sup> Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids.<sup>83</sup>

288. Despite such evidence, the Marketing Defendants have not acknowledged, retracted, or corrected their false claims that long-term opioid use improves functioning.

#### **8. Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids.**

289. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-

---

<sup>79</sup> Dowell, CDC Guideline, *supra*, at 2, 18.

<sup>80</sup> *Reducing the Risks of Relief*, *supra*, at 1503.

<sup>81</sup> Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

<sup>82</sup> Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine 2219–27 (Sept. 15, 2008), <https://www.ncbi.nlm.nih.gov/pubmed/18725868>.

<sup>83</sup> GM Franklin, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201–202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, <https://www.ncbi.nlm.nih.gov/pubmed/18197107>.



counter acetaminophen or over-the-counter or prescription non-steroidal anti-inflammatory drugs (“NSAIDs”).

290. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, the Marketing Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;”<sup>84</sup> hormonal dysfunction;<sup>85</sup> decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;<sup>86</sup> neonatal abstinence syndrome; and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.<sup>87</sup>

291. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the actual figure is closer to 3,200.<sup>88</sup>

292. Endo’s NIPC website, *Painknowledge.org*, contained a flyer called *Pain: Opioid Therapy*. This publication omitted significant adverse effects of opioids, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

---

<sup>84</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re: Docket No. FDA-2012-P-0818 (Sept. 10, 2013), [http://paindr.com/wpcontent/uploads/2013/09\\_FDA\\_CDOR\\_Response\\_to\\_Physicians\\_for\\_Responsable\\_Opioid\\_Prescribing\\_Partial\\_Petition\\_Approval\\_and\\_Denial.pdf](http://paindr.com/wpcontent/uploads/2013/09_FDA_CDOR_Response_to_Physicians_for_Responsable_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf).

<sup>85</sup> H.W. Daniell, 3(5) *J. Pain* 377-84 (2001), [https://www.jpain.org/article/S1526-5900\(02\)00032-9/fulltext](https://www.jpain.org/article/S1526-5900(02)00032-9/fulltext).

<sup>86</sup> See Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 *Eur. J. Pub. H.* 527-32 (July 31, 2014), doi:10.1093/eurpub/cku120, <https://www.ncbi.nlm.nih.gov/pubmed/25085470>.

<sup>87</sup> Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in U.S. Veterans of Iraq and Afghanistan*, 307(9) *J. Am. Med. Ass’n* 940-47, (Mar. 7, 2012) doi:10.1001/jama.2012.234, <https://jamanetwork.com/journals/jama/fullarticle/1105046>.

<sup>88</sup> Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 *Am. J. of Therapeutics* 17-25 (2004), <https://www.ncbi.nlm.nih.gov/pubmed/14704592>.

293. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*.<sup>89</sup> The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.<sup>90</sup>

294. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including a subject who was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. The article did not provide the same detail concerning the serious side effects associated with opioids.

295. Additionally, Purdue, acting with Endo, sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

296. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, while NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.<sup>91</sup>

---

<sup>89</sup> Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, [http://www.painmedicineweb.com/download/BtoB\\_Opana\\_WM.pdf](http://www.painmedicineweb.com/download/BtoB_Opana_WM.pdf) (link no longer available).

<sup>90</sup> *Id.*

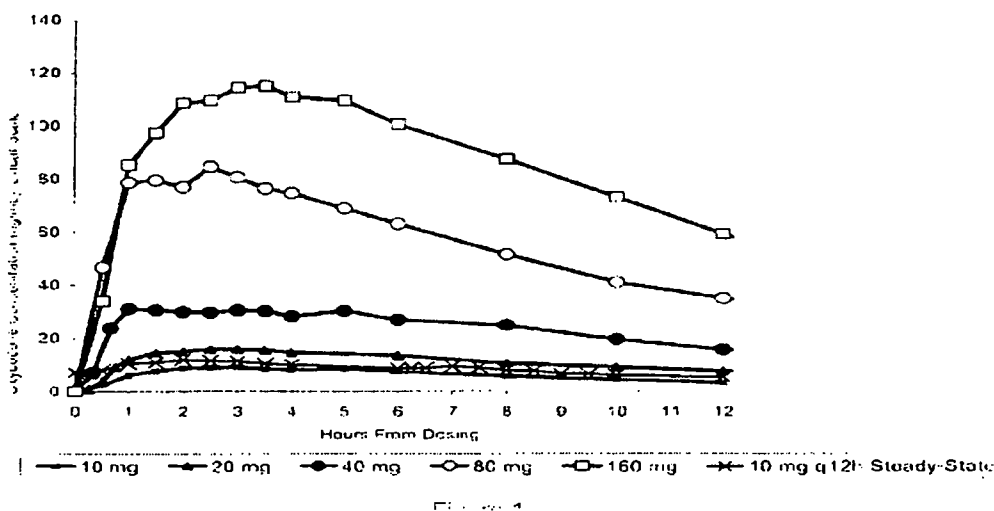
<sup>91</sup> M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013), <https://insights.ovid.com/pubmed?pmid=24025657> ("For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady."); see also, J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013), <https://www.ncbi.nlm.nih.gov/pubmed/23896698>.

### 9. Falsehood #9: OxyContin Provides Twelve Hours of Pain Relief.

297. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

302. Purdue promotes OxyContin as an extended-release opioid, but OxyContin does not produce a steady concentration of oxycodone (the active ingredient) in the body. Instead, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials, the concentration of the drug increases sharply at first and then tapers off over the course of twelve hours:

OxyContin PI Figure, Linear y-axis



303. The reduced concentration of oxycodone over time means that OxyContin no longer provides the same level of pain relief. As a result, in many patients, OxyContin's effect does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all relevant times.

304. OxyContin tablets initially release approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue in its original 1995 FDA-approved drug label claimed was more addicting. Second, the initial burst of oxycodone means that there is less of the drug available at the end of the dosing period. This decline in oxycodone concentration precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. In fact, the FDA found in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.

305. End-of-dose failure renders OxyContin even more dangerous because the withdrawal symptoms are followed by a euphoric rush with the next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing “the perfect recipe for addiction.”<sup>92</sup> Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall quantity of opioids they are taking.

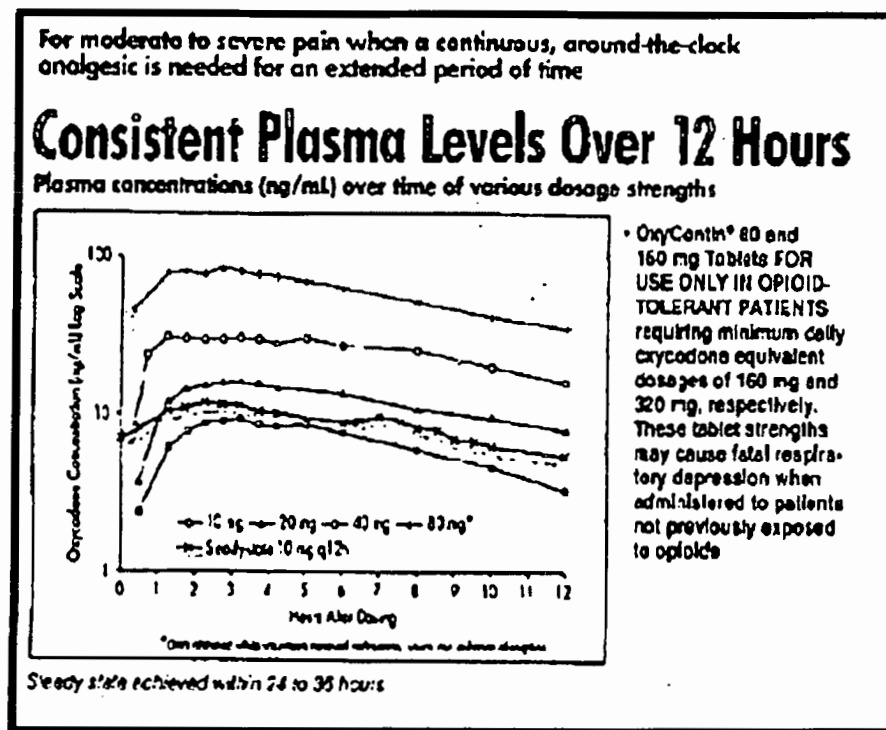
306. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

307. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma

---

<sup>92</sup> Harriet Ryan, et al., *‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1> (hereinafter, “*You Want a Description of Hell?*”).

Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version deceptively minimized the rate of end-of-dose failure by using a logarithmic scale to make it appear that the decline in oxycodone concentration over time is less than it actually is:



308. Purdue’s 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized “Q12h” dosing. These include an advertisement in the February 2005 *Journal of Pain* and the 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that “OxyContin’s positioning statement is ‘all of the analgesic efficacy of immediate-release oxycodone,

with convenient q12h dosing” and that “[t]he convenience of q12h dosing was emphasized as the most important benefit.”<sup>93</sup>

309. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. Higher dosing also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the Los Angeles Times, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED (morphine equivalent dose) that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”<sup>94</sup>

310. That OxyContin did not provide pain relief for a full twelve hours was known to Purdue and Purdue’s competitors, but was not disclosed to prescribers.

311. When some prescribers became aware that OxyContin did not provide twelve hours of pain relief, some began to prescribe it to be taken three times per day. Purdue’s knowledge of this tendency is apparent from MEDWATCH Adverse Event reports for OxyContin. Moreover, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” to prescribe OxyContin in shorter intervals and that the solution to inadequate pain control is higher doses.<sup>95</sup> One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!”<sup>96</sup>

312. Even Purdue’s competitor, Endo, was aware of the problem. Endo attempted to position its Opana ER drug as offering “durable” pain relief, by which Endo intended to suggest a

---

<sup>93</sup> Purdue Meeting Memo, *OxyContin Launch*, LOS ANGELES TIMES, May 5, 2016, available at <http://documents.latimes.com/oxycontin-launch-1995>.

<sup>94</sup> Dowell, CDC Guideline, *supra*, at 16.

<sup>95</sup> Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES, May 5, 2016, <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996>.

<sup>96</sup> *You Want a Description of Hell?*, *supra*.

contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour effect as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

313. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

**10. Falsehood #10: New Formulations of Certain Opioids Successfully Deter Abuse.**

314. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Purdue and Endo seized on them as an opportunity to compete. These companies developed and oversold “abuse-deterrent formulations” (“ADF”) as a solution to opioid abuse, as a reason for doctors to continue to “safely” prescribe their opioids, and as an advantage these expensive branded drugs possessed over other opioids. This false and misleading marketing of the benefits of ADFs preserved and expanded these companies’ sales and falsely reassured prescribers, thereby prolonging the opioid epidemic.

315. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

316. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, a former director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [i.e., ADF opioids] actually reduce rates of addiction, overdoses, or death.”

**a. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER**

317. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference in the label to supposed abuse-deterrent properties. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear that limited claims could be made about ADF because no evidence supported claims that ADF prevented tampering or oral abuse or reduced overall rates of abuse.

318. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to addressing the opioid crisis.

319. Despite its self-proclaimed good intentions, Purdue merely continued its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that Purdue's ADF opioids are non-addictive or less addictive;
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.



320. If pressed, Purdue acknowledged that perhaps some “extreme” patients might still abuse the drug but claimed that the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue’s ADF labels, its own information, and publicly available data.

321. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

322. In 2009, the FDA noted in permitting ADF labeling that “the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse).” In the 2012 medical office review of Purdue’s application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

323. The FDA’s Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in abuse,” given continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue’s funded research shows that half of OxyContin abusers continued to orally abuse the drug after the reformulation rather than shift to other drugs.

324. A 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The article revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

325. Websites and message boards used by drug abusers, such as *bluelight.org* and *reddit.com*, report a variety of ways to tamper with OxyContin and Hysingla ER to release their opioids immediately. Purdue has been aware of these methods of abuse for more than a decade.

326. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

327. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."<sup>7</sup> In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

328. Despite its own evidence of abuse and the lack of evidence regarding the benefit of ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

329. Purdue's recent advertisements in national newspapers also mislead prescribers, patients, payors, and the public by continuing to present its ADF opioids as evidence of its efforts to reduce opioid abuse.

#### **b. Endo's Deceptive Marketing of Reformulated Opana ER**

330. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains

---

<sup>7</sup> Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

331. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

332. Even prior to its approval, the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent.

333. Nonetheless, in August 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

334. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, the \$125 million that Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.<sup>98</sup> The FDA responded, "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."<sup>99</sup>

335. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version

---

<sup>98</sup> Pl.'s Opp. to Defs.' and Intervenor's Mots. to Dismiss and Pl.'s Reply in Supp. of Mot. for Prelim. Inj., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec. 14, 2012).

<sup>99</sup> Defs.' Resp. to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be “proud” that “almost all remaining inventory” of the original Opana ER had “been utilized.”<sup>100</sup>

336. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that the reformulation was less crushable to argue that it was developed for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”<sup>101</sup>

337. However, in a 2013 decision rejecting the petition, the FDA found that “study data show that the reformulated version’s extended-release features can be compromised when subjected to . . . cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

338. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER has increased by more than 500%. Endo’s own data, presented in 2014, found that between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.<sup>102</sup> The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, hepatitis C, and, in the case of reformulated Opana ER, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

<sup>100</sup> *Id.*; Endo News Release, Sept. 6, 2012 (Ex. J to Rurka Decl.), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

<sup>101</sup> Citizens Petition, FDA Docket 2012-8-0895, at 2.

<sup>102</sup> Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxycodone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014), <https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxycodone>.

339. Publicly, Endo sought to minimize the problem. On a 2013 call with investors, when asked about an outbreak of TEP in Ohio from injecting Opana ER, Endo sought to limit its import by ascribing it to “a very, very distinct area of the country.”

340. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based on the company’s detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

341. A review of national surveys of prescribers regarding their “take-aways” from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took away from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its “low abuse potential.” For example, a June 14, 2012 Endo press release announced “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

342. The press release further stated, “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers.” The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

343. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an Endo

press release, described Opana ER as “crush-resistant.” This article was posted on the website, which was accessible to patients and prescribers.

344. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana.

345. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.<sup>103</sup> Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.<sup>104</sup> However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

**c. Mallinckrodt’s Misrepresentations of Exalgo and Xartemis XR as Abuse Deterrents.**

346. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.”<sup>105</sup> One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”

347. With respect to Xartemis XR, Mallinckrodt’s promotional materials stated that “XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active

---

<sup>103</sup> Press Release, State of Ind. Health Dep’t, HIV Outbreak in Southeastern Indiana, (Feb. 25, 2015), [http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information\\_id=211489](http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489)

<sup>104</sup> Endo Provides Update on Opana ER, *supra*.

<sup>105</sup> Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt’s EXALGOR (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>.

ingredient from the large quantity of inactive and deterrent ingredients.”<sup>106</sup> In anticipation of Xartemis XR’s approval, Mallinckrodt added 150 to 200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”<sup>107</sup>

348. While the Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their “technology” addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

349. In sum, each of the ten categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. In addition, the Defendants’ misrepresentations and omissions as set forth in this Complaint are misleading and contrary to the labels of the Marketing Defendants’ products.

**B. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels.**

350. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or “detailers;” (2) “Front Groups” with the appearance of independence from the Marketing Defendants; (3) so-called Key Opinion Leaders (“KOLs”), that is, doctors paid by the Marketing Defendants to promote their pro-opioid message; (4) mechanisms of disseminating their misleading messages through reputable organizations; (5) CME programs controlled and/or funded by the Marketing Defendants; (6) branded advertising; (7) unbranded advertising; (8) publications; (9) speakers bureaus and programs; and (10) a clinical decision support alert system.

---

<sup>106</sup> *Responsible Use*, *supra*.

<sup>107</sup> Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL, (Dec. 30, 2013), <http://argencapital.com/mallinckrodt-banks-on-new-painkillers-for-sales>.

**1. The Marketing Defendants Used “Detailers” To Directly Disseminate Their Misrepresentations to Prescribers.**

351. The Marketing Defendants employed numerous sales representatives (also called “detailers”) in New York, including but not limited to the Sales Representative Defendants, to promote and sell opioids in New York.

352. Each Marketing Defendant promoted opioids through detailers and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that small group speaker programs were designed to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

353. In accordance with common industry practice, the Marketing Defendants purchased and closely analyzed prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allowed them to precisely track the rates of initial and renewal prescribing by individual doctors, allowing more targeted and tailored appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

354. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million to detail branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

355. At Purdue, aggressive and frequent visits to prescribers were always its most important marketing technique.

356. Each of these in-person sales visits cost Purdue money — on average more than \$200 per visit. But Purdue made that money back many times over because it convinced doctors to prescribe its addictive drugs. When Purdue identified doctors as profitable targets, Purdue visited



them frequently: often weekly, sometimes nearly daily. Purdue detailers asked doctors to list specific patients they were scheduled to see and pressed the doctors to commit to prescribing these patients Purdue opioids. By the time a patient walked into a clinic, the doctor, in Purdue's words, had already "guaranteed" that he or she would prescribe Purdue's drugs.

357. Purdue continued to incentivize its representatives to sell opioids even after some competitors had ended that practice. Representatives who failed to get enough patients on opioids were placed on probation, put on performance improvement plans, and threatened with termination if they did not generate more opioid sales. This was not an empty threat. In 2015 alone, Purdue replaced 14% of its sales representatives and 20% of its district managers for failing to generate enough opioid sales.

358. To make sure doctors prescribed more opioids, Purdue tracked their prescriptions, visited their offices, bought them meals, and asked them to put specific patients on Purdue drugs. Purdue selected doctors to target based on its estimates of which doctors could be influenced to increase opioid prescriptions the most. Purdue managers told representatives to visit most often the doctors who were most likely to change their prescribing to benefit Purdue. Purdue sales representatives visited Purdue's targets up to 200 times per year; those visits could cost Purdue up to \$40,000 annually per doctor. Purdue did not spend that amount of money so sales representatives could watch doctors write prescriptions that they were already going to write anyway. Instead, Purdue paid to lobby these doctors because Purdue knew its representatives would convince them to put more patients on opioids, at higher doses, for longer periods. Those extra prescriptions paid back Purdue's investment many times over.

359. In the fourth quarter of 2013, Purdue employed 632 sales representatives and, during that quarter, they visited prescribers 176,227 times – an annualized rate of over 700,000 visits. These statistics were regularly reported to the Sacklers and the Purdue Officers. Purdue executives told Mark Radcliffe and other sales managers that sales representatives should be committed to increasing opioid prescriptions. Purdue's budget for Sales and Promotion for 2013 was \$312,563,000. In 2013, Purdue

spent over \$9 million on meals alone for its prescribers.

360. Purdue intensified its marketing efforts in subsequent years, in an effort to counteract decreasing sales. For 2018, the Sacklers approved a target for sales representatives to visit prescribers 1,050,000 times – which on information and belief would include thousands of visits to New York prescribers — almost double the number of sales visits they had ordered during the peak of OxyContin sales in 2010.

## 2. The Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use.

361. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. The Marketing Defendants exerted influence and effective control over the messaging of these groups by providing major funding directly to them and to KOLs who served on their boards. These Front Groups put out patient education materials, treatment guidelines, and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.<sup>108</sup> Defendants funded these Front Groups in order to ensure supportive messages from seemingly neutral and credible third parties, and this funding did, in fact, ensure such supportive messaging—often at the expense of the Front Groups’ own constituencies.

362. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”<sup>109</sup> “Even small organizations— with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”<sup>110</sup>

<sup>108</sup> U.S. Senate Homeland Sec. & Governmental Affairs Comm., Ranking Members’ Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, at 3 (Feb. 12, 2018), <https://www.hsdl.org/?abstract&did=808171> (hereinafter “*Fueling an Epidemic Part Two*”).

<sup>109</sup> *Id.* at 2.

<sup>110</sup> *Id.*

363. A 2017 U.S. Senate investigation drew on disclosures from Purdue, Janssen, Insys,<sup>111</sup> and other opioid manufacturers to “provide[] the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy.”<sup>112</sup> The report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, found that the Marketing Defendants made millions of dollars’ worth of contributions to various Front Groups.<sup>113</sup>

364. The Marketing Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.<sup>114</sup> Such payments were part of a broad strategy by the Marketing Defendants to fund these Front Groups. For example, according to an internal Purdue presentation given in September 2010, between 2006 and 2010, the company spent \$24.5 million on education grants and donations, funding hundreds of requests annually.<sup>115</sup>

365. The Senate found that the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”<sup>116</sup> The report also found that these groups “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.”<sup>117</sup>

---

<sup>111</sup> Insys manufactured and marketed Subsys, a form of fentanyl. Its founder, John Kapoor, was sentenced to 66 months in prison for orchestrating a scheme to bribe doctors to prescribe his company’s product. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/founder-and-former-chairman-board-insys-therapeutics-sentenced-66-months-prison>.

<sup>112</sup> *Fueling an Epidemic Part Two*, *supra*, at 2.

<sup>113</sup> *Id.* at 3.

<sup>114</sup> *Id.* at 10.

<sup>115</sup> Purdue (Dr. J. David Haddox), *Health Policy* PowerPoint Presentation (Sept. 23, 2010), <https://www.finance.senate.gov/download/sfc0000212>.

<sup>116</sup> *Fueling an Epidemic Part Two*, *supra*, at 12–15.

<sup>117</sup> *Id.* at 12.

366. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted the Front Groups' false and deceptive messages. Defendants acted in concert with and through the Front Groups, each working with the other to deceptively promote the use of opioids for the treatment of chronic pain.

**a. American Pain Foundation**

367. The most prominent of the Front Groups was the American Pain Foundation ("APF").

368. The APF's 1998 business plan stated that "most pain sufferers are under-medicated" and that "many [physicians] are reluctant to prescribe opioids because they mistakenly think their patients will become addicted to the drug or because they fear investigation and sanctions by the regulatory bodies."<sup>118</sup> APF made it a three-year objective to reduce the "percentage of Americans who agree that it is easy to become addicted to pain medication."<sup>119</sup>

369. Although APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including Purdue, Endo, Janssen, and Cephalon.

370. In return, APF provided frequent and detailed updates, such as an accomplishments memo sent to Purdue president, Richard Sackler, highlighting multiple initiatives, including lobbying and public relations efforts to fight "misconceptions about [o]pioids in the [press]," noting that it sent background materials to 1,200 health journalists.<sup>120</sup>

371. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. The close

<sup>118</sup> American Pain Foundation, *1998 Business Plan*, at 3-2 (available at <https://www.finance.senate.gov/download/apf-1998-business-plan>).

<sup>119</sup> *Id.* at 7-2.

<sup>120</sup> American Pain Foundation, *2001 Accomplishments Report* (Feb. 18, 2002), available at <https://www.finance.senate.gov/download/apf-purdue-correspondence-2001-2005-apf65-111>.

relationship between APF and the Marketing Defendants demonstrates APF's lack of independence. Its willingness to allow the Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions.

372. APF was also instrumental in working with other Front Groups such as the Pain Care Forum, an informal, but powerful Washington, D.C.-based “coalition of drug manufacturers and other advocacy groups that met monthly to discuss opioid-related issues.”<sup>121</sup> At various times, its members included representatives multiple types of Defendants, including distributors and manufacturers.

373. In 2007, APF and Purdue collaborated on talking points for use at a Pain Care Forum meeting. Some of these talking points included “[o]verly restrictive regulatory policies impeded pain relief;” “doctors and people with pain” who “believe that opioid medications are addictive” constituted “barriers to effective pain care;” and opioid medications “give relief – not a ‘high.’”<sup>122</sup>

374. APF also developed NIPC, which ran a facially unaffiliated website, *painknowledge.org*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited<sup>123</sup> prescriber education programs, including a series of “dinner dialogues.” But it was Endo that substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing the programs' content; and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or on *painknowledge.org*. Endo estimated it would reach 60,000 prescribers through NIPC.

---

<sup>121</sup> *December 2020 Senate Bipartisan Opioids Report, supra*, at 5.

<sup>122</sup> *Id.*

<sup>123</sup> Accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies.

375. APF was often called upon to provide “patient representatives” for the Marketing Defendants’ promotional activities, including for Purdue’s *Partners Against Pain* and Janssen’s *Let’s Talk Pain*. Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that shared its business interests.

376. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

377. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF’s work related to a specific promotional project. Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF’s funding) for any reason.

378. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

379. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and opioid manufacturers. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective

immediately.” Without support from the Marketing Defendants, to whom APF could no longer be useful, APF was no longer financially viable.

**b. American Academy of Pain Medicine and the American Pain Society**

380. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants.

381. Through 2019, AAPM received lavish funding: Purdue paid \$2,798,769, J&J paid \$570,174; Janssen paid \$83,475; Insys paid \$52,725. Endo funded AAPM CMEs. Teva is on AAPM’s corporate relations council and contributed over \$1 million. Payments by opioid manufacturers to AAPM totaled nearly \$10 million through 2019.<sup>124</sup>

382. As to APS, Purdue paid \$3,418,210; J&J paid \$1,793,906; Endo paid \$5,208,065; Janssen paid \$60,000. Altogether, opioid manufacturers contributed over \$12 million to APS through 2019.<sup>125</sup>

383. AAPM’s corporate council includes Purdue, Depomed, Teva, and other pharmaceutical companies. AAPM’s past presidents include Dr. J. David Haddox (1998), Dr. Scott Fishman (2005), Dr. Perry G. Fine (2011), and Dr. Lynn R. Webster (2013), all of whom have well-documented connections to opioid manufacturers.

384. Dr. Fishman, who also served as a KOJ. for the Marketing Defendants, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”<sup>126</sup>

385. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present

---

<sup>124</sup> *December 2020 Senate Bipartisan Opioids Report, supra*, at 19–37.

<sup>125</sup> *Id.*

<sup>126</sup> Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), <http://www.medscape.org/viewarticle/500829>.

educational programs at an off-site dinner symposium in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

386. AAPM describes its annual meeting as an “exclusive venue” for offering CME programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

387. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through their significant and regular funding and through the leadership of pro-opioid KOIs within the organization.

388. In 1996, AAPM and APS jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk of addiction to opioids was low. Dr. Haddox, who co-authored the statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011.

389. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). The 2009 Guidelines, with Defendants' assistance, prompting, involvement, and funding, continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOI Dr. Fine, received support from the Marketing Defendants: six from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

390. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine and who served on the AAPM/APS Guidelines panel, has since described the 2009 Guidelines as “skewed” by drug companies and “biased in many important respects,” including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.



391. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online.

392. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids and whose lack of specialized training in pain management and opioids made them more reliant on and less able to evaluate these guidelines. For that reason, the CDC has recognized that treatment guidelines can “change prescribing practices.”<sup>127</sup> The 2009 Guidelines are relied upon by doctors.

393. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support the Guidelines’ conclusions, the Marketing Defendants’ involvement in the development of the Guidelines, or their financial backing of the Guidelines’ authors. For example, a 2009 speaker presentation prepared by Endo, *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain*, used the 2009 Guidelines while omitting their disclaimer about the lack of evidence for recommending the use of opioids for chronic pain.

### c. Federation of State Medical Boards

394. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. These boards have the power to license doctors, investigate complaints, and discipline physicians.

395. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

396. Since 1998, the FSMB has been developing guidelines for the use of opioids for treating pain. The 1998 version, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines did not teach that opioids are only appropriate in limited cases after other treatments have

---

<sup>127</sup> Dowell, CDC Guideline, *supra*.

failed, but rather that opioids are “essential” for treating of chronic pain, including as a first prescription option. A 2004 iteration of the 1998 Guidelines made the same claims. FSMB’s guidelines were posted online and were available and intended to reach physicians nationwide, including those in New York. Purdue paid \$100,000 for the printing and distribution of FSMB’s Guidelines.<sup>128</sup>

397. FSMB’s 2007 publication, *Responsible Opioid Prescribing*, was backed largely by drug manufacturers, including Purdue, Endo and Cephalon, and also made claims similar to those in the 1998 Guidelines.

398. The publication also received support from APF and AAPM. The publication was written by Dr. Fishman; Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards.<sup>129</sup> The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated; and that patients should not be denied opioid medications, except in light of clear evidence that such medications are harmful to the patient.<sup>130</sup>

399. The Marketing Defendants used the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but that no discipline would result if opioids were prescribed as part of an ongoing patient relationship in which prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

---

<sup>128</sup> John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), <https://www.medpagetoday.com/neurology/painmanagement/31256>.

<sup>129</sup> Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf> (hereinafter, “Email from Dr. Scott Fishman to Charles Ornstein”).

<sup>130</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide*, 8–9 (2007).

400. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of interest in his authorship of the book. This is because prior to 2011, he had been scrutinized for his involvement with Front Groups and manufacturers and for accepting payments from them.<sup>131</sup>

401. The Marketing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB \$822,400.06 over 8 years.<sup>132</sup> Cephalon paid FSMB \$180,000 over a 3-year period, 2007-2008 and 2011.<sup>133</sup> Endo paid FSMB \$371,620 over a 5-year period.<sup>134</sup> Mallinckrodt paid FSMB \$100,000 in 2011.<sup>135</sup>

**d. The Joint Commission and the Pain & Policy Study Group of the University of Wisconsin**

402. The Joint Commission f/k/a the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO” prior to 2007 and “Joint Commission” thereafter) is the oldest and largest healthcare standards-setting and performance-improvement organization in the United States. It accredits and certifies approximately 21,000 public and private health care organizations and programs in the United States. One of its principal purposes is the accreditation of hospitals.

403. Because the Joint Commission accredits 99% of health care organizations in the United States, most hospitals view losing Joint Commission accreditation as a disaster because accredited hospitals that are statutorily deemed to be in compliance with federal requirements and so are eligible to participate in Medicare and Medicaid programs without a separate government inspection.

404. Because compliance with Joint Commission standards on an annual basis is critical for hospitals, for drug manufacturers and those in the supply chain who profit from drug sales getting the

<sup>131</sup> Email from Dr. Scott Fishman to Charles Ornstein, *supra*.

<sup>132</sup> Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), <https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html>.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

Joint Commission to promulgate and enforce standards that make the use of their drug product necessary to meet those standards is an ideal path to lucrative sales.

405. As a result, Defendants made it their paramount goal in the late 1990s to influence JCAHO to enact standards making pain the “fifth vital sign,” thereby encouraging the use of opioids to treat that pain.

406. The Marketing Defendants advanced their campaign of deception to influence JCAHO to enact these pain standards through Front Groups such as APF, the American Pain Society (“APS”), and the Pain and Policy Study Group of the University of Wisconsin (“UW-PPSG”), whose efforts to advocate for the assessment and treatment of pain and to minimize the risks of addiction from opioids were financed primarily by the Robert Wood Johnson Foundation.

407. Payments were made to secure the support of these Front Groups. In 1997, Purdue paid \$48,501 to APS and \$75,000 to UW-PPSG to start efforts to enact pain standards at FMSB and JCAHO. It followed with another \$75,000 contribution to UW-PPSG and \$75,960 to APS in 1998. J&J contributed \$146,215 to APS in 1997 and a whopping \$480,905 in 1998. Endo gave \$20,000 to APS in 1998.<sup>136</sup>

408. Supported by these entities and the efforts of the Marketing Defendants, FMSB enacted its 1998 Pain Guidelines, and JCAHO enacted Pain Guidelines in 1999, co-authored by the National Pharmaceutical Council (“NPC”), another Front Group. Because the JCAHO Guidelines totally transformed the standard of care for treating pain in hospitals and other healthcare organizations, their effective date was delayed until 2001. In the interim, JCAHO, the Marketing Defendants, and Front Groups and KOIs supported by the Marketing Defendants engaged in a well-financed effort to persuade hospitals, prescribers, and even consumers to adopt the message embodied in the new standards: opioids should be used to treat pain and were not addictive when so used.

409. The Marketing Defendants provided additional financial support to JCAHO while it was developing a pain care guide and other materials to be distributed to hospitals and pain care

---

<sup>136</sup> *December 2020 Senate Bipartisan Opioids Report, supra*, at 19–23.

providers. Purdue reported paying over \$2.1 million directly to JCAHO from 2000 to 2002, including \$560,000 in 2000; \$981,359 in 2001; and \$582,649 in 2002. J&J contributed \$14,919 in 2001, and Endo contributed a total of \$75,000 in 2000 and 2001 and another \$500,325 in 2011. Janssen, NPC, Pfizer, and Abbott also directly contributed.<sup>137</sup> J&J contributed \$498,791 to JCAHO in 2011 to support JCAHO's continued efforts to enforce its guidelines on healthcare organizations that it certified, including hospitals.

410. This support paid off for the Marketing Defendants because the resulting guide claimed that "[s]ome clinicians have inaccurate and exaggerated concerns" regarding addiction and that "[t]his attitude prevails despite the fact that there is no evidence that addiction is a significant issue when persons are given opioids for pain control."<sup>138</sup>

411. In October 2001, Purdue paid \$58,272 to fund the publication of a book, *Pain Assessment and Management: An Organizational Approach*. It also paid \$85,000 to fund two videos in August 2000 for "Pain Management in Special Populations: Geriatric and Disease Related Pain."<sup>139</sup>

412. In 2001, Ortho McNeil (now Janssen) provided \$66,000 in funding for "Pain Management: An Overview for Clinicians" audioconference.<sup>140</sup>

413. NPC paid \$155,104 between 2001 and 2002 for JCAHO to develop "a monograph designed as a reference for clinicians, quality professionals, researchers and others involved in performance assessment, improvement, education, and policy decisions related to pain management within healthcare organizations."<sup>141</sup>

414. The Marketing Defendants further supported these activities with payments to UW-PPSG, FMSB, and other Front Groups intended to implement the change in the standard of care for treating pain forced by the 1998 FMSB and 1999 JCAHO pain standards. For example, Purdue's total

---

<sup>137</sup> *Id.* at 19–37.

<sup>138</sup> *Id.* at 6–7.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* (quoting letter from Mark Chassin, President, The Joint Commission, to Senator Baucus and Senator Grassley (June 2012)).

contribution to UW-PPSG from 1997 to 2012 was \$2,054,178, including \$175,000 in 2001; \$85,024 in 2002; \$280,000 in 2003; \$282,220 in 2004; \$670,388 in 2005; and \$142,500 in 2006. In addition, Purdue gave a total of \$904,742 to FSMB to support their activities relative to their 1998 Pain Guidelines, including \$199,895 in 2004; \$339,000 in 2005; \$50,000 in 2006; and \$100,000 in 2007. Endo contributed to UW-PPSG a total of \$666,965 through 2012, including a total of over \$230,000 between 2001 and 2004.<sup>142</sup> Loss of accreditation by JCAHO can require a hospital to expend enormous resources to become reaccredited.

415. As a result of the Marketing Defendants' efforts to manipulate the standard of care, many hospitals, including Plaintiffs, risked loss of their JCAHO accreditation if they did not incorporate the "fifth vital sign" standard and put pain at the forefront of their treatment.

416. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States had been able to accomplish.<sup>143</sup> However, during its routine survey, JCAHO found that the hospital was not adequately documenting follow up questions after prescribing pain medications to patients.<sup>144</sup> As a result, the hospital was given only one quarter to bring their compliance up to 90%.<sup>145</sup> They could not, placing their JCAHO accreditation at risk for the entire hospital, despite their 99% satisfaction rate.

417. Since 2001, JCAHO standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants' campaign could not be undone. Dr. David W. Baker, JCAHO's executive vice president for health care quality evaluation, explains that "the concept that iatrogenic addiction was rare and that long

<sup>142</sup> *Id.* at 7, 19–37.

<sup>143</sup> Testimony of Tim Westlake, U.S. Senate Comm. on Homeland Sec. and Gov't Affairs (Apr. 15, 2016), <https://www.hsgac.senate.gov/imo/media/doc/Testimony-Westlake-2016-04-15-REVISED.pdf>.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later.”

**e. Alliance for Patient Access**

418. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”<sup>146</sup> It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.<sup>147</sup> As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J, Endo, Mallinckrodt, Purdue, and Cephalon.

419. APA’s board members have also directly received substantial funding from pharmaceutical companies.<sup>148</sup> For instance, board vice president Dr. Srinivas Nalamachu (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from Endo, Purdue, Cephalon, and nonparty Insys. Nalamachu’s clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed an Insys opioid.<sup>149</sup> Other board members have included Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Mallinckrodt, and Cephalon; Dr. Howard Hoffberg from Maryland, who

<sup>146</sup> The Alliance for Patient Access, *About A/P/A*, <http://allianceforpatientaccess.org/about-afpa/#membership> (last accessed August 1, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

<sup>147</sup> Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, HEALTH NEWS REVIEW (Oct. 2, 2017), <https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> (hereinafter “Jaklevic, *Non-profit Alliance for Patient Access*”).

<sup>148</sup> All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica’s Dollars for Docs database, <https://projects.propublica.org/docdollars/>.

<sup>149</sup> Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR, July 19, 2017, <http://www.kansascity.com/news/business/health-care/article162569383.html>.

received \$153,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Purdue, Mallinckrodt, and Cephalon, and Insys; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

420. Among its activities, APA issued a white paper, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*.<sup>150</sup> Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

\*\*\*

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.<sup>151</sup>

421. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.<sup>152</sup>

<sup>150</sup> Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), <http://1yh21u3cjpvt3xjder1dco9mx5s.wpengine.nerdna-cdn.com/wp-content/uploads/2013/01/PT-White-Paper-Final.pdf>.

<sup>151</sup> *Id.* at 4–5 (footnote omitted).

<sup>152</sup> *Id.* at 5–6.



422. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.<sup>153</sup>

The white paper concludes that “[p]rescription pain medications, and specifically opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”<sup>154</sup>

423. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While ostensibly given for protecting patients’ access to Medicare and touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of Congress who supported the APA’s agenda.<sup>155</sup>

424. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. (“CSA” or “Controlled Substances Act”).<sup>156</sup> The AAPM was also a signatory to this letter. An internal DOJ memo stated that the proposed bill “could actually result in increased diversion, abuse, and public health and safety consequences,”<sup>157</sup> and, according to DEA

<sup>153</sup> *Id.* at 6.

<sup>154</sup> *Id.* at 7.

<sup>155</sup> Jaklevic, *Non-profit Alliance for Patient Access*, *supra*.

<sup>156</sup> Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

<sup>157</sup> Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by->

Chief Administrative Law Judge John J. Mulrooney, the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like Defendants here, in the courts.<sup>158</sup> In part due to APA’s lobbying efforts, the bill became law in 2016.

425. Although purporting to be a physician-advocacy organization, APA’s funding stream tied it to the Marketing Defendants and other drug manufacturers. For instance, in 2017, all of APA’s approximately \$2 million in revenue was generated from contributions and grants, 90% of which were from pharmaceutical manufacturers. Three opioid makers led the way: Teva (\$40,000), Mallinckrodt (\$75,000), and Pfizer (\$40,000).<sup>159</sup> In addition, between 2012 and 2018, Abbott contributed \$705,000; Mallinckrodt contributed \$615,000; Teva “gave” \$500,000; and Purdue gave \$165,000.<sup>160</sup>

426. APA manages a coalition called the Alliance for Balanced Pain Management, which it acquired from Mallinckrodt in 2016. As part of the acquisition, Mallinckrodt paid APA \$200,000 to support the coalition and to pay for an annual summit that the coalition hosts. It describes its mission as advocating for “balanced pain management by supporting organizations and individuals who share a common goal to reduce pain, reduce medicine abuse and improve care.”<sup>161</sup> According to a December 2020 Senate Bipartisan Finance Committee Opioids Report, its members include patient groups such as the American Chronic Pain Foundation and U.S. Pain Foundation, which have strong financial ties to opioid manufacturers. It is led by a Steering Committee that includes several individuals who have received about \$480,000 from opioids manufacturers.<sup>162</sup>

#### **f. U.S. Pain Foundation**

427. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections to and interpersonal relationships with the Marketing Defendants.

---

drug-industry-and-congress. Hereinafter, “Opioid Crisis Fuel.”

<sup>158</sup> J. John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

<sup>159</sup> December 2020 Senate Bipartisan Opioids Report, *supra*, at 12.

<sup>160</sup> *Id.* at 26.

<sup>161</sup> *Id.* at 14–15.

<sup>162</sup> *Id.*

428. USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3 million between 2012 and 2015 alone.<sup>163</sup> Drug and device manufacturers contributed a total of over \$6.3 million to USPF between 2012 and 2018. Insys contributed \$3,250,000 during that period; Abbott contributed \$919,500 from 2014 to 2018; Teva paid \$789,000; Purdue gave \$249,6000 from 2012 to 2018; J&J contributed \$192,000; Endo “gave” \$130,000; and Janssen paid \$7,500 in 2014.<sup>164</sup>

429. USPF was also a critical component of the Marketing Defendants’ lobbying efforts to reduce limits on over-prescription.

430. USPF advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e., Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.<sup>165</sup> Front Groups like AAPM, APS, and PhRMA are also USPF members.

#### **g. American Geriatrics Society**

431. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections to and interpersonal relationships with the Marketing Defendants.

432. AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue, and Janssen. Between 1997 and 2012, Purdue contributed a total of \$443,548 to AGS; J&J contributed \$565,626; and Endo paid \$341,785.<sup>166</sup> Purdue paid an additional \$11,785 from 2012-2017<sup>167</sup> and provided \$40,000 in “corporate roundtable dues” to AGS’s Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.<sup>168</sup>

433. AGS contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002, *The Management of Persistent Pain in Older Persons* (“2002 AGS

---

<sup>163</sup> *Fueling an Epidemic Part Two*, *supra*, at 4.

<sup>164</sup> *December 2020 Senate Bipartisan Opioids Report*, *supra*, at 37.

<sup>165</sup> *Fueling an Epidemic Part Two*, *supra*, at 12; U.S. Pain Foundation, *Transparency*, <https://uspainfoundation.org/transparency/> (last accessed on August 1, 2018).

<sup>166</sup> *December 2020 Senate Bipartisan Opioids Report*, *supra*, at 22–23.

<sup>167</sup> *Fueling an Epidemic Part Two*, *supra*.

<sup>168</sup> Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017) (hereinafter, “Lundebjerg Letter”).

Guidelines”), and 2009, *Pharmacological Management of Persistent Pain in Older Persons* (“2009 AGS Guidelines”).<sup>169</sup>

434. AGS’s common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies as that would suggest drug company influence. Instead, AGS opted to accept commercial support to disseminate pro-opioid publications.

435. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable even for patients with a prior history of drug abuse.<sup>170</sup> These Guidelines further advised that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in Google Scholar since their 2009 publication.

436. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members. For example, Dr. Bruce Farrell was an AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo and helped conduct a Purdue-funded CME for treating osteoarthritis pain.<sup>171</sup>

437. Representatives of the Marketing Defendants, often at informal meetings during conferences, suggested activities, lobbying efforts, and publications for AGS to pursue. AGS then

---

<sup>169</sup> B Ferrell, et al., *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on August 1, 2018) (hereinafter “2009 AGS Guidelines”).

<sup>170</sup> 2009 AGS Guidelines, *supra*, at 1342.

<sup>171</sup> *Narcotic Painkiller Use Booming Among Elderly*, *supra*.

submitted grant proposals to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these meetings.

438. Members of the AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or as speakers for medical events. As described below, many of the KOIs also served in leadership positions within the AGS.

#### **h. American Chronic Pain Association**

439. The American Chronic Pain Association ("ACPA") is an example of a Front Group overtaken by those whose mission was to expand the use of opioid painkillers to those with chronic pain, consistent with the FMSB, JHACO, and other pain guidelines that the opioid industry influenced.

440. After ACPA was founded in 1980, it became influenced by the opioid industry through their contributions. The organization received funding from opioid makers, medical device manufacturers, and companies that market opioid therapies for opioid-related conditions. These payments funded materials that "appear to help sell products sold by opioid manufacturers, discussed opioid therapy while sidestepping the addictive nature of drugs, and attributed responsibility for overdoses for people who misuse opioids."<sup>172</sup>

441. Between 2012 and 2018, contributions to ACPA totaled \$3,193,795 and included the following amounts from Marketing Defendants: Teva (\$1,005,975); Endo (including Endo Labs, \$399,250); Purdue (\$386,470); Pfizer (\$214,875); J&J (\$120,000); Depomed (\$67,500); Mallinckrodt (\$55,775); Janssen (\$25,000); Abbott (\$15,000); and Cephalon (\$10,000).<sup>173</sup>

442. Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than \$140,000 from opioid manufacturers, including Endo.

#### **i. National Pharmaceutical Council**

443. The National Pharmaceutical Council ("NPC") is an organization of pharmaceutical companies styled as a "policy research organization." Its functions include "information

---

<sup>172</sup> *December 2020 Senate Bipartisan Opioids Report, supra*, at 10–12 (and authorities cited therein).

<sup>173</sup> *Id.* at 31.

dissemination” to benefit its members. Upon information and belief, most of the Marketing Defendants (including but not limited to Allergan, Abbott, Mallinckrodt, J&J, and Teva) are or have been members of the NPC during the relevant time period. NPC is currently funded by, among others, J&J, Purdue, and Teva.

### **3. The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use.**

444. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. Pro-opioid doctors have been centerpieces of the Marketing Defendants’ scheme since its inception and were used to create the grave misperception that science and legitimate medical professionals favored the wider and broader use of opioids. These doctors, known as Key Opinions Leaders (“KOLs”) include Drs. Russell Portenoy, Lynn Webster, Perry Fine, and Scott Fishman.

445. Although funded by the Marketing Defendants, the KOLs were used to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

446. As the Marketing Defendants’ false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and were placed on boards of pro-opioid advocacy groups and professional societies that developed, selected, and presented CMEs.

447. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of the various modalities through which doctors receive their information.

448. In return for their pro-opioid advocacy, the Marketing Defendants’ KOLs received money, prestige, recognition, research funding, and avenues to publish, enabling them to push the Marketing Defendants’ deceptive message out to the medical community.

449. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content published by these KOLs. Of course, the Marketing Defendants also kept these KOLs well-funded.

450. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs' studies or articles to drive prescriptions of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles as if they were independent medical literature so that they would be well-received by the medical community. The Marketing Defendants did not support, acknowledge, or disseminate truly independent publications critical of chronic opioid therapy.

451. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs either knew that their statements were false and misleading or recklessly disregarded their truth or falsity. Nevertheless, these KOLs continued to publish their misstatements to benefit themselves and the Marketing Defendants.

452. The following KOLs were funded in whole or in part by the following companies. The boxes marked with an X indicate that the given company paid the given KOL:

	Janssen	Purdue	Teva	Endo	Mallinckrodt	Teva/ Cephalon
Foley	x	x				x
Portenoy	x	x		x		
Joransson	x					
Dahl		x				
Webster		x	x	x	x	x

	Janssen	Purdue	Teva	Endo	Mallinckrodt	Teva/ Cephalon
Fine	x	x		x		
Fishman	x	x				
Haddox		x				

**a. Dr. Russell Portenoy**

453. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while simultaneously serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”<sup>174</sup>

454. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.<sup>175</sup>

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”<sup>176</sup>

<sup>174</sup> Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

<sup>175</sup> Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247–87 (H.J. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

<sup>176</sup> *Id.*



455. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”<sup>177</sup>

456. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”<sup>178</sup>

457. Dr. Portenoy was also a critical component of the Marketing Defendants’ control over their Front Groups. He sat as a director on the APF board and was the APS president.

458. In recent years, some of the Marketing Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.<sup>179</sup> Dr. Portenoy has now admitted that he minimized the risks of opioids<sup>180</sup> and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”<sup>181</sup> He mused, “Did

---

<sup>177</sup> *Dreamland*, *supra*, at 314.

<sup>178</sup> *Id.* at 136.

<sup>179</sup> See, e.g., John Fauber, *Painkiller boom fueled by networking*, MILWAUKEE J. SENTINEL, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

<sup>180</sup> Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER, Nov. 8, 2013, <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic>.

<sup>181</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, THE WALL STREET JOURNAL, Dec. 17, 2012, <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . .”<sup>182</sup>

459. In a 2011 interview, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn’t before. *In essence this was education to destigmatize opioids, and because the primary goal was to destigmatize, we often left evidence behind.*<sup>183</sup>

460. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to have always to live with that one.”<sup>184</sup>

#### b. Dr. Lynn Webster

461. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was president of AAPM in 2013 and is still a board member. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo’s special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

462. Dr. Webster created and promoted the *Opioid Risk Tool*, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term,

---

<sup>182</sup> *Id.*

<sup>183</sup> Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWx9D4w&feature=youtu.be>.

<sup>184</sup> *Pain Killer*, *supra*, at 277.

and for this reason, references to screening appear in various industry-supported guidelines. Versions of this tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented a webinar sponsored by Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended risk screening tools, urine testing, and patient agreements to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors at hospitals such as Plaintiffs.

463. Dr. Webster is himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants’ promotional messages, Dr. Webster apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids; he prescribed staggering quantities of pills.

**c. Dr. Perry Fine**

464. Dr. Perry Fine’s ties to the Marketing Defendants are well documented. He has authored articles, testified in court cases and before state and federal committees, and argued against legislation restricting the prescription of high doses of opioids to non-cancer patients. He has served on Purdue’s advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo; he has served in similar capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and sat on the board of directors of APF.<sup>185</sup>

465. Multiple videos feature Dr. Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith before her death did not make her an addict.

466. Dr. Fine has also acknowledged failing to disclose numerous conflicts of interest, including to his own employer, the University of Utah. For example, he told the university that he had

---

<sup>185</sup> Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true> (hereinafter “*Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*”).

received under \$5,000 in 2010 from J&J for providing “educational” services, but J&J’s website states that the company paid him \$32,017 that year for consulting, promotional talks, meals, and travel.<sup>186</sup>

467. Drs. Fine and Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, which downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.<sup>187</sup>

468. In November 2010, Dr. Fine and others presented the results of a Cephalon-sponsored study in article titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”<sup>188</sup> In this article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP [breakthrough pain] in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain.”<sup>189</sup> The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades;” (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain;” and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic

---

<sup>186</sup> Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter “Weber, *Two Leaders in Pain*”).

<sup>187</sup> Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia*, at 20, 34, (McGraw-Hill Companies 2004), [http://www.thblack.com/links/RSD\\_OpioidHandbook.pdf](http://www.thblack.com/links/RSD_OpioidHandbook.pdf).

<sup>188</sup> Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010), [https://www.jpainjournal.com/article/S0885-3924\(10\)00390-8/fulltext](https://www.jpainjournal.com/article/S0885-3924(10)00390-8/fulltext).

<sup>189</sup> *Id.*

pain.”<sup>190</sup> The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” It also concluded that the number of abuse-related events was “small.”<sup>191</sup>

469. Multiple videos feature Dr. Fine delivering educational talks about opioids. In one video from 2011, *Optimizing Opioid Therapy*, he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) for both cancer and non-cancer patients and suggesting it may take four or five switches over a person’s “lifetime” to manage pain.<sup>192</sup> He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.”<sup>193</sup> The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”<sup>194</sup>

#### d. Dr. Scott Fishman

470. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are multitudinous. He has served as an APF board member and as AAPM president and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA*.<sup>195</sup>

---

<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube.com (Nov. 8, 2012), <https://www.youtube.com/watch?v=G3II9yqgXI>.

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion, supra*; Weber, *Two Leaders in Pain, supra*.

471. In 2007, Dr. Fishman authored *Responsible Opioid Prescribing*, a physician's guide on the use of opioids to treat chronic pain that promoted long-term opioid treatment as a viable and safe option.

472. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.<sup>196</sup>

473. The updated guide still assures physicians that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins."<sup>197</sup>

474. In another guide, Dr. Fishman continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical copier' and an addict."<sup>198</sup> The guide also continues to present symptoms of addiction as symptoms of "pseudoadddiction."

#### **4. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs.**

475. Now that the Marketing Defendants had collected a group of physician promoters and built up a false body of "literature," they needed to ensure their false message was widely distributed.

476. One way the Marketing Defendants aggressively distributed their false message was through countless continuing medical education ("CME") programs.

477. Doctors are required to attend CME programs each year to remain licensed. These programs are generally delivered in person (often in connection with professional organizations'

---

<sup>196</sup> Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians* 10–11 (2012).

<sup>197</sup> *Id.*

<sup>198</sup> Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (2012).

conferences), online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to learn about new developments or to deepen their knowledge in specific areas of practice. Because CMEs are taught typically by KOLs who are highly respected in their fields, they can be especially influential with doctors who believe that the presentations reflect these physicians' expertise.

478. The countless doctors and other health care professionals who participate in accredited CMEs constituted an enormously important audience for the Marketing Defendants' opioid reeducation campaign. They particularly targeted general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

479. The Marketing Defendants sponsored CMEs that were delivered thousands of times; these CMEs promoted chronic opioid therapy by supporting and disseminating the deceptive and biased messages described in this Complaint. While often generically titled to relate to the treatment of chronic pain, these CMEs focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

480. The American Medical Association has recognized the impropriety that pharmaceutical-company-funded CMEs create. It has stated that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urged that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."<sup>199</sup>

481. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

---

<sup>199</sup> Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).



482. By sponsoring CME programs put on by Front Groups including APF and AAPM, the Marketing Defendants expected and understood that instructors would deliver pro-opioid messages, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOI.s to give talks that supported chronic opioid therapy. Producers of CMEs and the Marketing Defendants measured the effects of CMEs on prescribers' view of opioids and their absorption of specific messages. This measurement confirms the strategic rationale for the Marketing Defendants' support of CMEs.

**5. The Marketing Defendants Used Branded Advertising to Promote Their Products to Doctors and Consumers.**

483. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *J.M.I.* The Marketing Defendants collectively spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they had spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

484. The Marketing Defendants' advertising also targeted consumers. The Marketing Defendants knew that physicians were more likely to prescribe a drug if a patient specifically requested it.<sup>290</sup> They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.<sup>291</sup> Endo's research, for example, found that direct-to-consumer advertising resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and

---

<sup>290</sup> In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it compared with 1% of those making no specific request. J.B. McKinlay, et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) *Med. Care* 294 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151257>.

<sup>291</sup> *Id.*



support” materials in the form of pamphlets, videos, or other publications that patients could view in their physicians’ offices.

#### **6. The Marketing Defendants Used Unbranded Advertising to Promote Opioid Use for Chronic Pain Without FDA Review.**

485. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” that generally touted the benefits of opioids without specifically naming a particular brand-name drug.

486. Unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product. As a result, there is no requirement to provide balanced disclosures about the product’s limits and risks. In contrast, a “branded” advertisement that identifies a specific medication must also include its indication (i.e., the condition which the drug is approved to treat) and possible side effects and contraindications—what FDA Guidance refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label.

487. By using unbranded materials to avoid these restrictions, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy.

488. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website, *inthefaceofpain.com*. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue had paid them hundreds of thousands of dollars.

#### **7. The Marketing Defendants Funded, Edited, and Distributed Publications That Supported Their Misrepresentations.**

489. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was

calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

490. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement in academic journals of favorable but deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

491. The Marketing Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in marketing departments.

492. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

#### **8. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.**

493. In addition to making sales calls, the Marketing Defendants' detailers also identified doctors to serve, for payment, on speakers' bureaus and to attend programs with speakers with meals paid for by the Marketing Defendants.

494. These speaker programs and associated speaker trainings served three purposes: 1) as an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) as an opportunity for doctors to be selected to attend forum at which the drug companies could further market to the speaker; and 3) as an opportunity for the doctors to market to their peers.

495. The Marketing Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage.

496. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide for activities such as participating on speakers' bureaus and providing consulting services.

**9. The Marketing Defendants Conspired with Practice Fusion to Spread Their Deceptive Messages.**

497. Beginning in and around Fall 2013, Practice Fusion and Purdue worked together to create and embed a clinical decision support alert (referred to hereafter as the "Pain CDS") in Practice Fusion's electronic health records to prompt doctors to consider prescribing Purdue's opioids for their patients.

498. A clinical decision support system provides automated recommendations to physicians to improve their treatment of patients. The Pain CDS suggested that doctors focus on assessing and treating a patient's pain symptoms and provided the doctor with a list of potential care plan treatment options, including opioids manufactured by Purdue such as OxyContin, Butrans, and Hysingla.

499. In or around May 2014, Practice Fusion forwarded to Purdue news stories concerning Practice Fusion's implementation of a CDS alert paid for by a vaccine manufacturer. The article was forwarded within Purdue to an executive-level corporate officer with the message: "I know you know of Practice Fusion, we too are working to get our pain management tools into their platform." The executive responded, "Thanks. The key is understanding how it grows or protects scripts."

500. In a March 23, 2015 email, a Practice Fusion employee explained that Purdue "has communicated that the average dosage of OxyContin is declining" and that "[p]roviders are hesitant about using high dosages to combat pain for a variety of reasons, mostly, political pressure. . . . As a result, Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and before every [prescription]."

501. On March 31, 2015, Practice Fusion made a presentation to Purdue indicating that a new pain CDS could be "based on" the "brand objectives" of Purdue's extended-release opioid

products, including targeting “opioid naïve patients” and patients who were using immediate release opioids (“IROs”).

502. Purdue confirmed that it wished to use Practice Fusion CDS to target opioid naïve and IRO users as potential new users of Purdue’s extended-use opioids (“EROs”). Practice Fusion recommended creating a CDS alert to help Purdue reach its commercial goals. Practice Fusion’s model estimated that Purdue could achieve “patient gain” of 2,777 Purdue ERO users, amounting to between \$8,458,232 and \$11,277,645 in additional opioid revenue, from funding a Pain CDS with Practice Fusion, a significant return on investment—between 5.8 and 7.8 times of Purdue’s cost of funding the proposed Pain CDS.

503. On or about July 16, 2015, Practice Fusion personnel emailed Purdue’s marketing department regarding the Pain CDS, stating, “We feel that the proposed program can help meet the strategic commercial needs of the pain franchise at Purdue.”

504. On September 1, 2015, two Practice Fusion employees traveled to Purdue headquarters and proposed that Purdue pay Practice Fusion approximately \$1 million to develop and implement a Pain CDS to influence healthcare providers to prescribe more EROs.

505. Purdue and Practice Fusion entered into a written statement of work contracting for the Pain CDS effective March 1, 2016. According to Practice Fusion’s guilty plea, Purdue paid \$959,700 for a program to identify patients for chronic pain management treatment with Purdue’s opioids. Practice Fusion understood and has admitted that Purdue provided remuneration in exchange for the Pain CDS because the Pain CDS could boost sales of Purdue’s opioids.

506. Purdue did not pursue a CDS alert with Practice Fusion to assist doctors in screening patients for risk of opioid addiction or opioid abuse. Instead, Purdue sought Practice Fusion’s Pain CDS to increase sales of its extended-release opioid products. Practice Fusion’s recap of its initial conference call with Purdue regarding designing this project stated that the “success” of the Pain CDS program would be “increased prescriptions for Purdue meds.” A summary circulated within both companies stated that the “[p]rimary goal of the project is to increase Rx for Purdue’s medications.”

507. The Pain CDS that was developed with Purdue's marketing department violated clinical guidelines at the time that it went live on or about July 6, 2016. It did not include recommendations from the CDC Guideline or from those published in the 2016 *NEJM* article, "Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies." Instead, the Pain CDS advocated the use of Purdue's EROs for patients with less than severe pain; disregarded whether the patient's pain could be adequately treated by non-opioid products; listed Purdue's EROs for patients who had never before received opioid therapy; and recommended Purdue's EROs as options for patients without chronic pain if they had had any other acute pain complaints within the prior three months.

508. In short, the Pain CDS encouraged healthcare professionals to increase prescriptions of Purdue's opioid products because Purdue paid Practice Fusion to do so. Evidence-based guidelines and applicable clinical quality measures ("CQMs") at the time advocated just the opposite: limited use of Purdue's EROs.

509. On or about December 14, 2016, Practice Fusion personnel made a presentation to Purdue reporting that, from July 2016 to November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients and 97,000 healthcare providers. Practice Fusion explained that since Pain CDS alerts went into effect, "there is a general shift toward EROs from [immediate-release opioids]." Practice Fusion also reported on its analysis of the effectiveness of EROs for lowering pain, finding that they were the least effective for lowering pain, as only 39.17% of patients treated had lower pain. Their data also showed EROs were the second least effective treatment option for lowering pain for patients with chronic pain, lowering pain for only 40.41% of patients.

510. Practice Fusion understood and admitted that it was unlawful to sell clinical decision support programs based on anticipated returns on investment that pharmaceutical companies, such as Purdue, might achieve. Clinical decision support programs must be consistent with any applicable evidence-based medical guidelines, including the Centers for Medicare and Medicaid Services' CQMs.

511. The Pain CDS continued well after Allscripts acquired Practice Fusion.

512. While operational from July 2016 to Spring 2019, the rigged Pain CDS popped up to make recommendations to doctors more than 230 million times. Not surprisingly, the health care providers receiving the alerts prescribed EROs at a higher rate than those who did not receive them.

513. On November 6, 2017, Practice Fusion and Purdue employees reported at a national American Medical Informatics Association Annual Symposium in Washington, D.C. that their study of the effectiveness of the Pain CDS on Practice Fusion's platform had "a sustained influence on the rate of opioid prescribing."

514. On January 27, 2020, Practice Fusion paid \$145 million to resolve criminal and civil investigations asserting that the Pain CDS arrangement and thirteen others like it constituted an illegal kickback scheme and that it had conspired with Purdue Pharma to violate § 371 of the Anti-Kickback Statute.

**C. The Marketing Defendants Directly Targeted Hospitals.**

515. From the beginning, hospitals were directly targeted by the Marketing Defendants.

516. Internal documents from the 1995 "OxyContin Launch" orchestrated by Purdue and Abbott identified (1) hospital pharmacists as among their "audience;" (2) hospitals among their "institutional targets;" (3) an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months;" and (4) an objective of developing a "successful distribution program" to hospitals.

517. The coordinated efforts of the Marketing Defendants, Front Groups, and KOLs led JCAHO's and FSMB's guidelines and created demand for narcotic painkillers to treat chronic pain. The activities of each of these Front Groups and KOLs are described in greater detail *supra*.

518. For hospitals and the doctors who practice in them, the primary vehicle through which the Marketing Defendants collectively accomplished this result was through the creation and enforcement of guidelines for the treatment of pain by JCAHO. In 2001, due to the influence of the Marketing Defendants, JCAHO, along with NPC "introduced standards for [hospitals] to improve their care for patients with pain." The new standards for hospitals put patient pain front and center as

the “fifth vital sign.” This monograph, *Pain: Current Understanding of Assessment, Management and Treatments*, required assessment of pain in all patients.

519. In 2000, Purdue sponsored a JCAHO book that claimed that “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”<sup>202</sup> It also called doctors’ concerns about addiction side effects “inaccurate and exaggerated.”<sup>203</sup>

520. Dr. David W. Baker, JCAHO’s executive vice president for health care quality evaluation, has since acknowledged that JCAHO “was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information.”<sup>204</sup>

521. In 1996, Purdue made a deal with Abbott under which Abbott’s sales force would promote Purdue’s lead opioid, OxyContin, in hospitals. This course of conduct is discussed in more detail *infra*.

**D. The Marketing Defendants’ Goal Was for More Patients to Take More Opioids at Higher Doses for Longer Periods of Time.**

522. The Marketing Defendants wanted more patients to take more opioids at higher doses and for longer periods of time. They sought to achieve this in two ways: (1) increasing the patient population; and (2) increasing dosages quickly to keep patients on opioids longer.

**1. Increasing the Patient Population**

**a. The Marketing Defendants Focused on Elderly Patients.**

523. Elderly patients frequently suffer from osteoarthritis, but opioids are not approved to treat that condition. Purdue conducted a single study on osteoarthritis for its Butrans opioid, and it failed. Purdue admitted in internal documents that its opioids “are not indicated for a specific disease” and that “it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or

---

<sup>202</sup> Sonia Moghe, *Opioid history: From ‘wonder drug’ to abuse epidemic*, CNN (Oct. 13, 2016), <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

Osteoarthritis.” Nevertheless, to meet its business goals, Purdue trained its representatives to mislead doctors by promoting opioids for osteoarthritis without disclosing Purdue’s failed trial.

524. Purdue also directed sales reps to use marketing materials that highlighted patients with osteoarthritis. At one point, the Purdue Individuals wanted to know if sales reps could sell more by remaining silent about the failed Butrans trial: “What can be said in response to a prescriber who asks directly or indirectly, ‘can this product be prescribed for my patient with OA [osteoarthritis]?’ In responding are we required to specifically mention the failed trials in OA?”

**b. The Marketing Defendants Focused on “Opioid-Naïve” Patients.**

525. In order to expand the market for their drugs, the Marketing Defendants worked to change the perception of opioids from a last resort for cancer patients and the terminally ill to a “first line” medication suitable for widespread use.

526. A particularly insidious aspect of Purdue’s focus on “naïve” patients and on keeping patients on opioids longer was its savings card program. The cards provided a discount on a patient’s first five prescriptions. In 2012, Purdue’s internal ten-year plan highlighted its discovery that opioid savings cards kept patients on opioids longer: “more patients remain on OxyContin after 90 days.” The savings card program was incredibly lucrative. The return on investment for Purdue was 4.28, so that every \$1,000,000 given away in savings came back to Purdue as \$4,280,000 in revenue—because patients stayed on dangerous opioids longer. Discounts could have cut Purdue’s revenue if patients took opioids only for a short time. But because the card program kept patients on opioids longer, Purdue profited.

**2. Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer**

527. Purdue staff, from sales representatives to senior management (including the Purdue Individuals), regularly and candidly discussed the imperative of increasing prescribed dosages. Accordingly, Purdue’s second most important sales tactic (after frequent detailing, Purdue’s most important strategy) was to cause prescribers to prescribe higher doses. This was manifested in Purdue’s



*Individualize the Dose* campaign and was communicated to prescribers in detailers' visits. Sales representatives were relentlessly pressured to increase the average doses prescribed in their territories.

An aspect of this strategy was to encourage faster upward titration—moving quickly from smaller to larger doses. The lowest dosage of Purdue's Butrans product, for example, was described to prescribers as an "introductory" dose that would presumptively be increased for most if not all patients.

528. The Marketing Defendants' focus on increasing dosages and increasing the duration of opioid usage had devastating consequences for patients. Patients exposed to higher dosages and for longer periods of time are many times more likely to become addicted and to overdose.

**E. The Marketing Defendants' Scheme Succeeded, Creating a Public Health Epidemic.**

**1. The Marketing Defendants' Influence Dramatically Expanded Opioid Prescribing and Use.**

529. The Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and they worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

530. Each of the Marketing Defendants actively tracked the impact of their marketing efforts on doctors' perceptions and prescribing habits. They purchased prescribing and survey data that allowed them to closely monitor these trends. For instance, they monitored doctors' prescribing before and after detailing visits and before and after speaker programs. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., how many doctors believed that opioids had a low abuse potential), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more opioids, and persuaded them not to stop prescribing opioids or to respond to concerns by switching to allegedly "safer" opioids, such as ADI's. The unsupported claims of ADI's greater safety are discussed *supra*.

531. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.<sup>205</sup> The effects of sales calls on prescribers' behavior is well documented in the literature. One study examined four practices: visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in prescribing practices and in requests by physicians to add drugs to hospitals' formularies.

532. The Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.<sup>206</sup> This response is the direct result of the Marketing Defendants' fraudulent marketing campaign.

533. Thus, both independent studies and the Marketing Defendants' own tracking confirm that their scheme dramatically increased their sales.

<sup>205</sup> See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014), [https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0939?url\\_ver=Z39.88-2003&rft\\_id=ori%3Arid%3Acrpub%3Dpubmed&rft\\_dat=crpub%3Dpubmed](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0939?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Acrpub%3Dpubmed&rft_dat=crpub%3Dpubmed) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC262274/> (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls) (hereinafter "*Commercial Triumph*").

<sup>206</sup> CS Hwang, et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), <https://www.ncbi.nlm.nih.gov/pubmed/25485657>.

## 2. The Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

534. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found a "very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."<sup>217</sup> It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

535. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."<sup>218</sup>

536. In a 2016 report, the CDC explained, "Opioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to revers[ing] the epidemic of opioid drug overdose deaths and prevent[ing] opioid-related morbidity."

537. These studies among others above demonstrate that the actions of the Marketing Defendants had a direct and proximate causal effect on prescriptions of opioids, that the initial effects of false marketing engaged in by the Marketing Defendants persist over time through the transitions in the epidemic from prescription opioids to heroin to fentanyl, and that false marketing engaged in by the Marketing Defendants directly and proximately led to increased overdose deaths and the spread of the opioid epidemic.

---

<sup>217</sup> Theodore J. Cicero, et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 *Pharmacoepidemiology & Drug Safety* 827-40 (2007).

<sup>218</sup> See *A Proactive Response*, *supra*.

**F. Each of the Marketing Defendants Made Materially Deceptive Statements and Concealed Material Facts.**

538. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

539. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and, therefore, were more likely to accept the Marketing Defendants' misrepresentations about the risks and benefits of opioids.

**1. Purdue**

540. Purdue made and/or disseminated deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and misrepresented the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through unbranded publications and internet sites that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction,

even in high-risk patients;

- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced assessment of the long-term and dose-dependent risks of opioids versus non-opioid pain relievers;
- g. Providing significant financial support to pro-opioid KOLs who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing essential financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life and that concealed contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Disseminating misleading statements in education materials to hospital

doctors and staff while purportedly educating them on new pain standards;

- q. ~~Developing and embedding clinical decision support alert software through Practice Fusion's electronic health records system in order to prompt doctors to consider prescribing Purdue's opioids for their patients;~~
- r. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- s. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs that Purdue knew would reach these same prescribers.

541. More specifically, Purdue made and/or disseminated deceptive statements and promoted a culture that misled doctors and patients into believing opioids were a safe treatment for chronic pain, including, but not limited to, the following:

- a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. After Purdue submitted a second version of the video, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.<sup>209</sup>
- b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that “fewer than one per cent” of patients who took OxyContin became addicted.
- c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative at Brandeis University, has worked with hundreds of patients addicted to opioids. He has stated that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. “If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off,” Kolodny said. “It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical

---

<sup>209</sup> *Empire of Pain, supra.*

community about the risks.”<sup>210</sup>

- d. “Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn’t. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug’s safety with literature that had been produced by doctors who were paid, or funded, by the company.”<sup>211</sup>
- e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid \$40 million in bonuses to its sales representatives.<sup>212</sup>
- f. By 2003, the Drug Enforcement Administration found that Purdue’s “aggressive methods” had “very much exacerbated OxyContin’s widespread abuse.” Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had “deliberately minimized” the risks associated with the drug.<sup>213</sup>

542. “From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue’s national speaker bureau. It is well documented that this type of pharmaceutical

---

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> *Commercial Triumph, supra.*

<sup>213</sup> *Empire of Pain, supra.*



company symposium influences physicians' prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."<sup>214</sup>

543. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	\$1,091,024.86
American Academy of Pain Management	\$725,584.95
ACS Cancer Action Network	\$168,500.00 <sup>215</sup>
American Chronic Pain Association	\$312,470.00
American Geriatrics Society	\$11,785.00 <sup>216</sup>
American Pain Foundation	\$25,000
American Pain Society	\$542,259.52
American Society of Pain Educators	\$30,000
American Society of Pain Management Nursing	\$242,535.00
The Center for Practical Bioethics	\$145,095.00
U.S. Pain Foundation	\$359,300.00
Washington Legal Foundation	\$500,000.00
TOTAL	\$4,153,554.33

544. Purdue streamed videos to doctors on its OxyContin Physicians Television Network and hired the most prolific opioid prescribers as spokespersons to promote its drugs to other doctors.

<sup>214</sup> *Commerical Triumph, supra*.

<sup>215</sup> Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

<sup>216</sup> The AGS reported that Purdue also provided \$40,000 in "corporate roundtable dues" to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. *See Lundebjerg Letter, supra*.



545. In May 2007, Purdue and three of its executives pled guilty to federal criminal charges for misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay nearly \$635 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. At the time, this was one of the largest settlements with a drug company for marketing misconduct.<sup>217</sup> Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, Purdue's former medical director, pled guilty and agreed to pay \$7.5 million in fines.

546. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills, which were a prime target for diversion.

547. Purdue took no action to report such prescribers. For example, despite its knowledge of illicit prescribing from a Los Angeles clinic that its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement had shut it down and not until the ring had prescribed more than 1.1 million OxyContin pills.

## 2. Abbott

548. On January 1, 1996, Abbott entered into a "Co-Promotion Agreement" with Purdue to market OxyContin using a dedicated sales force focused on hospitals and their doctors. Under the Co-Promotion Agreement, Abbott's hospital products division would expand the market for OxyContin well beyond the existing market, which was then limited to cancer patients and patients facing end-of-life pain. Pursuant to that agreement, between 1996 and 2002, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

---

<sup>217</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

549. During this time, Abbott helped turn OxyContin into the largest-selling opioid in the nation. Under the agreement, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25% to 30% of all net sales for prescriptions written by doctors its sales force called on until 2002 with a residual payment of 6% of net sales up through at least 2006. These residual payments suggest Abbott's intent that doctors would continue prescribing OxyContin even after Abbott's direct promotion ceased.

550. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.2 billion in 2002. Over the life of the Co-Promotional Agreement, Purdue paid Abbott nearly half a billion dollars.

551. Abbott and Purdue's conspiring with Pharmacy Benefit Managers ("PBMs") to drive opioid use is well established:

Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction.

....

One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try and make parameters [for prescribing] less stringent."<sup>218</sup>

552. Abbott sales staff were instructed about the euphoria patients were receiving on the shorter-acting painkiller, Vicodin, and were told they should tell the physician that "OxyContin has fewer such effects." Abbott's head of pain sales taught his staff that OxyContin would "minimize[e] the risk of dependence" and "lower[] euphoria" when, in fact, he had little knowledge of pharmacology and no basis for these statements.

---

<sup>218</sup> American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, PSYCHOLOGY TODAY (Oct. 28, 2016), <https://www.psychologytoday.com/blog/side-effects/201610/americas-opioid-epidemic>.

553. Abbott's co-promotion of OxyContin was, in the words of Abbott's counsel, dedicated to "hospitals, surgical centers and hospital-based surgeons." Promoting the use of OxyContin for "postoperative pain" and "support[ing] the Abbott agreement" were paramount objectives identified in Purdue's internal documents. "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies."<sup>219</sup> Initial plans called for marketing to "[a]ll 1,200 cancer centers," "[a]ll 1,200 major teaching institutions," and "[a]ll 2,500 community hospitals with  $\geq$  100 beds." The hospital marketing plan further entailed the following actions:

- a. The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.
- b. Educate MD's/RN's/RPH's regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available, clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.
- c. Educational lectures should be held through the Speakers' Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers' Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.
- d. Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD's/RN's/RPH's and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.
- e. Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

---

<sup>219</sup> 2002 Purdue Budget Plan, <https://khn.org/news/purdue-and-the-oxycontin-files> (last visited Aug. 20, 2018) (emphasis added).

554. Abbott, in a 1997 document, indicated that prescriptions written by “Abbott MD’s” comprised 25% of all OxyContin prescriptions. In addition, Purdue’s budget records reveal the payments to Abbott for its OxyContin work, which were termed “commissions.” From 1996 through 2002, Abbott was paid \$374 million in “commissions;” total sales of the drug during that time were nearly \$5 billion. From 2003 to 2006, OxyContin sales were nearly \$6 billion. From 1996 to 2005, Abbott’s “commissions” exceeded \$500 million.

555. The importance of targeting hospitals was illustrated by a study that “demonstrated that patients who receive an opiate prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription.”<sup>220</sup>

556. Abbott heavily incentivized its staff to push OxyContin, offering \$20,000 cash prizes and luxury vacations to top performers. Abbott’s almost religious zeal to sell the drug is evident in the wide use of terminology from the Crusades of the Middle Ages: Sales reps were called “royal crusaders” and “knights” in internal documents, and they were supervised by the “Royal Court of OxyContin” – executives referred to in memos as the “Wizard of OxyContin,” “Supreme Sovereign of Pain Management,” and the “Empress of Analgesia.” The head of pain care sales, Jerry Eichhorn, was the “King of Pain” and signed memos simply as “King.”

557. An internal document reveals Abbott’s inappropriately jocular attitude toward the opioid crisis being created by decorating the executives’ portraits with crowns and a wizard’s hat:

---

<sup>220</sup> *Opioid Exit Plan, supra*, at 593.



558. From the very beginning, Purdue and Abbott intended to position OxyContin as useful for more than just cancer pain. Internal documents from the 1995 "OxyContin Launch" indicate that they also intended it for a "secondary market . . . for non-malignant pain (musculoskeletal, injury and trauma)" and "reinforced that we do not want to niche OxyContin just for cancer pain." In 1996, Purdue envisioned OxyContin being prescribed for a long laundry list of conditions and literally generated a "wish list" of clinical studies to support prescription in a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the "Abbott agreement" to market to hospitals, removing "the prohibition of giving the product during the 12-24 hour immediate postop period," and removing "the qualification limiting the indication to pain for more than a few days;" (2) "nonmalignant pain" (including low back pain and osteoarthritis); and (3) HIV/AIDS treatment.

559. Working closely with Purdue, Abbott played a central role in establishing the market for opioids, without which there would be no epidemic in New York. In 1995, Abbott conducted a "commercial review" of the viability of the promotion of OxyContin for acute postoperative pain and concluded that such use of OxyContin would be inappropriate. Despite these concerns, Abbott

recognized that a commercial relationship with Purdue to promote the purchase of vast amounts of OxyContin could be very profitable for Abbott and entered into the Co-Promotion Agreement.

560. Abbott requested to review Purdue's sales aids used to promote all forms of OxyContin in order to make sure each aid met with Abbott's approval prior to being distributed.

561. Abbott regularly sent sales records and sales call records regarding OxyContin, OxyContin IR, and Oxyfast to Purdue for Purdue's use in its sale and distribution of those drugs.

562. Instead of being forthcoming with information regarding the addictive nature of OxyContin after newspaper and electronic media reports regarding OxyContin and addiction began to be released, Abbott instructed its sales representatives to avoid any discussion of abuse or diversion unless the called-upon physician specifically brought the subject up first. If doctors did raise concerns, Abbott instructed its representatives to downplay them and to describe such instances as "abuse," which did not happen with "true pain patients." Abbott made these statements despite the lack of any scientific support.

563. Abbott's sales representatives would also plan and host events such as outings to professional sporting events for targeted physicians and staff. The representatives gave other incentives such as flashlights and 15- and 30-dollar phone cards. Abbott funded dinners for surgeons, selling them on OxyContin while waiting on the food. Representatives would also purchase and send lunch and/or snacks to potential proscribing doctors' offices.

564. Abbott and Purdue required intense efforts from Abbott sales representatives, including devoting fifty percent of their daily time to marketing OxyContin products and keeping up an average of six sales physician and/or clinic meetings a day.

565. In order to allay physician concerns regarding OxyContin and addiction, Abbott requested, received, and used training materials in the form of a presentation from Purdue, *Handling Abuse, Addiction and Diversion Issues – Manager Meeting Workshop*.

566. Abbott agreed to market OxyContin to hospitals, specifically targeting anesthesiologists, surgeons, emergency room doctors, and orthopedists to convince these doctors to

begin to prescribe OxyContin for long-term, chronic pain. To accomplish this, Abbott agreed to dedicate a group of three hundred detailers and twenty “hospital integrated systems executives” to call on hospitals and doctors across the country. In detailing hospitals and their doctors, Abbott supplied its representatives with IMS Health data reflecting the prescribing data for the targeted doctors.

567. Abbott was not a passive partner. Through efforts it described as a promotional “blitz,” Abbott’s sales representatives worked closely with Purdue to aggressively promote OxyContin.

568. Abbott sales directors and managers and Purdue management met quarterly throughout the contract term to discuss future sales materials in development, how to benefit from market research, and how to develop unmet needs to increase the purchase of OxyContin.

569. Over the life of the Co-Promotion Agreement, Abbott did not rely solely upon Purdue’s training materials. Abbott and Purdue examined market research and data in order to fine tune promotional materials. Abbott worked with a third party to create and use an adult learning module-type program to make its sales calls more effective. Abbott received sales and profit information that revealed that Abbott’s sales calls were very effective in expanding the market for OxyContin. Sales continued to remain strong in both hospital and retail markets during and after the Co-Promotion Agreement.

570. Part of Abbott’s duties under the contract was to build “good will” regarding OxyContin so that even after the contract expired, Purdue could maintain a relationship with physicians and entities whom Abbott and Purdue intended to keep purchasing OxyContin. This was accomplished, in part, by Abbott providing Purdue with Abbott sales call records and notes in both electronic and paper formats.

571. Abbott’s efforts to solidify Purdue’s future sales of OxyContin, expand the market for OxyContin, and influence the standard of care for prescription of OxyContin were successful. Abbott’s efforts substantially contributed to the maintenance of the expanded market for OxyContin for treatment of chronic pain until 2018 when Purdue stopped marketing OxyContin to prescribers.

572. On information and belief, many patients prescribed OxyContin as a result of the Co-Promotion Agreement remain dependent on opioids, thereby continuing the damage caused by Abbott and Purdue's actions.

573. Abbott also assisted Purdue by recruiting doctors to participate in studies regarding new uses for OxyContin. These studies were used to convince other doctors to prescribe OxyContin. For instance, in November 1997 Abbott distributed an "OxyContin post PCA" study to promote OxyContin use following surgery. Abbott also recruited doctors to promote OxyContin through CME seminars.

574. Abbott made deceptive statements regarding the risks of Oxycontin in order to expand the market into chronic care. Abbott instructed its sales representatives to detail doctors with the message that OxyContin provided a slower peak in oxycodone blood concentration, "a lower peak concentration," and slower concentration decrease than a comparable dose of immediate-release oxycodone; for instance, in a 1999 handout Abbott noted that short-acting Schedule III opioids had a higher abuse potential. Sales representatives were to tell doctors that the lack of a high peak also lowered the incidence of side effects and the abuse potential. At the time of those representations, however, no studies or scientific data supported them.

575. Abbott's training manuals highlighted the "delayed absorption" language from the OxyContin label and claimed that "slower absorption may lessen abuse risk." Abbott's training materials described the statement regarding "iatrogenic addiction" (i.e., addiction arising out of a legitimate prescription) not as a warning about risk, but simply as a "reminder to the physician that addiction as a result of legitimate medical use is very uncommon, and not to mistake tolerance, physical dependence, or attempt by the patient to obtain adequate analgesia as signs of addiction."

576. Abbott provided its sales representatives with an OxyContin visual aid in titled "24 hours of pain relief THE HARD WAY," which included a graph that used a logarithmic scale to depict blood plasma concentrations of OxyContin over time as flatter than they actually were, thereby supporting the misrepresentation that OxyContin provided twelve full hours of pain relief. The piece



also asserted that “100% of all clinical patients were dosed Q 12 H in clinical trials”—something which was not true.

577. Abbott also instructed its representatives to “[t]ell your doctor that with its longer half-life Oxycontin has fewer such [euphoric] effects” than its competitors such as Vicodin.

578. Abbott further instructed sales representatives to tell doctors that the “sustained analgesia that OxyContin provides helps minimize the risk of patient dependence because patients don’t have to keep dodging themselves to achieve and maintain pain relief more than twice daily.”

579. Abbott trained its sales representatives to state that OxyContin was “less habit-forming” than other opioids and that “less than 1% [of patients] become addicted.”

580. Abbott, along with Purdue, pursued postoperative studies to support a supplemental new drug application that would remove the restriction on OxyContin for immediate post-operative pain. Abbott and Purdue pursued this change in spite of growing reports of OxyContin addiction.

581. Abbott provided its sales representatives with reprints to give to doctors, one of which was a piece written by Purdue KOL Dawn Marcus. This article advocated using long-acting opioids for the treatment of chronic pain and stated, without citation, “While studies report drug abuse/dependence/addiction in 3 to 19 percent of chronic pain patients, true addiction (psychologic dependency) is uncommon with the use of long-acting opioids for chronic pain.”

582. Abbott’s website touted that OxyContin was “co-promoted by Purdue Pharma L.P and Abbott Laboratories” and that Abbott’s “pain management therapies are safe, effective and easy to use.” Abbott recommended that OxyContin Tablets were “for patients with moderate to severe pain requiring opioid therapy for more than a few days.”

583. Beginning in 2000, Abbott continued to aggressively market OxyContin, but in addition to the above measures, it also utilized JCAHO’s new pain-care standards. Abbott instructed its sales force to leverage the new pain guidelines by reminding doctors and hospitals that if did not treat pain they could risk the hospital’s accreditation.

584. These efforts were so effective that when bad press ultimately started to be received by Abbott about OxyContin abuses, Abbott sales representatives worked with Purdue representatives to investigate abuse; they found that negative press was not changing the prescribing habits of OxyContin prescribers.

585. Abbott knew as early as 1999 that OxyContin was being improperly shared between patients but when confronted with this knowledge, Abbott chose to adjust its selling points to insist that doctors should weigh the high value of patient's pain relief with OxyContin against the chance of pills being shared.

586. Abbott's efforts to expand and establish the market for OxyContin resulted in a flood of OxyContin. The market which Purdue and Abbott created persists to this day, substantially contributing to the opioid epidemic.

587. On or about October 20, 2020, Abbott's marketing partner, Purdue, pleaded guilty to federal criminal charges relating to the marketing of OxyContin and other opioid products. Purdue faces penalties of approximately \$8.2 billion. This is the second time that Purdue has pleaded guilty to federal criminal charges.

### **3. Endo**

588. Defendant Endo made and/or disseminated deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long-term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately

conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus non-opioid pain relievers;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, but that concealed contrary data;
- l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Using in-person detailing to make deceptive statements to prescribers concerning the use of opioids to treat chronic non-cancer pain.

589. Endo provided at least \$31 million in funding to NIPC between 2001 and 2012. Linda Kitlinski, Endo's former Director of Clinical Development and Education and NIPC's direct contact person at Endo, testified that the strategy for Opana ER was to "refocus the attention to the appropriate clinical use of opioid analgesics." In an email, she indicated that "educational programs that are not done through an 'independent third-party' will be perceived as inappropriately promotional" and agreed with her colleagues that "opioids should be the focus of the new NIPC module." NIPC made the following false statements regarding opioids generally, without focusing on brand names or generics: (1) "Addiction to opioids in the context of acute pain treatment is rare in those with no history of addictive disorder"; (2) describing as "pseudoaddiction" a patient's pattern of drug-seeking behavior and suggesting such behavior is merely a sign of "inadequate pain management"; and (3) a patient's "level of function should improve" after long-term opioid use, allowing him or her to "participate in activities of daily living, such as work and hobbies."

590. Endo utilized APF to spread its message by supporting the publication of a *Pain Action Guide*, which included misrepresentations: "Pain medications rarely cause addiction.... Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed."

591. Endo personnel stated that promotion of brand-name opioids created a sales "pie," part of which "converts immediately to the generic flavor." The share of the pie that goes to generic opioids almost always increases over time. And, although Endo's generics were not marketed directly to physicians, there was some sales effort directed by the national account executives to retailers and wholesalers.

592. Endo sales representatives and marketing materials informed prescribers that its opioids would improve patient functioning, but failed to discuss addiction risk. Sales representatives also falsely told prescribers that other analgesics were more toxic than opioids. Endo funded the distribution of *Responsible Opioid Prescribing* and *Exit Wounds*, both of which contain misrepresentations about opioid benefits and addiction risk.

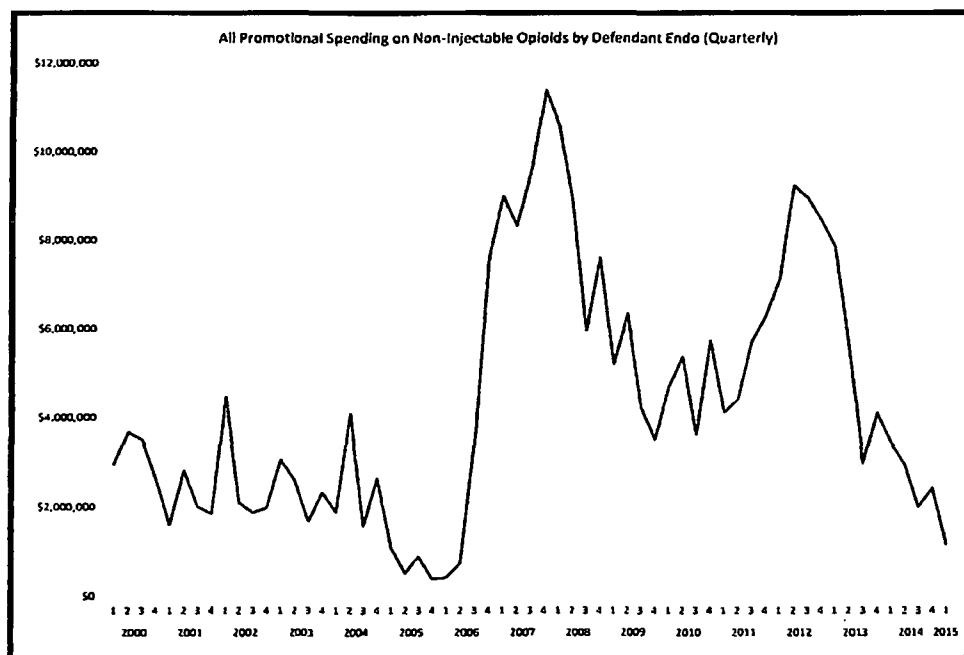
593. Endo sponsored a pain website, *painknowledge.com*, which asserted that opioid treatment will improve a patient's functioning and that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website made similar misleading statements about addiction risk. Endo-sponsored CMEs likewise promised improved functioning and deceptively minimized addiction risk. One such CME stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." Endo also distributed a pamphlet edited by KOI. Dr. Russell Portenoy that falsely implied that patients taking opioids for pain relief will not become addicted.

594. Even after becoming aware of its widespread abuse, Endo continued to aggressively promote Opana. The New York Attorney General found that Endo knew, as early as 2011, that Opana ER was being abused, but that certain sales representatives who detailed New York health care providers did not know about any policy or duty to report problematic conduct. Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER). In 2016, Endo entered into a settlement agreement with the New York State Attorney General regarding its unsupported advertising claims. Endo paid a penalty and agreed to refrain from making statements in New York in any training or marketing that: 1) Opana ER or opioids generally are non-addictive; 2) most patients who take opioids do not become addicted; or 3) use the term pseudo-addiction.

595. Even after the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of Opana and requested its removal from the market in 2015 "based on its concern that the benefits of the drug may no longer outweigh its risks," Endo continued to market the drug until 2017.

596. Endo's commitment to disseminating the false narrative surrounding opioids is illustrated by the vast sums it spent on promotion. As shown on the graph below, Endo's quarterly spending went from a still substantial \$2 million to \$4 million between 2000 and 2004 before escalating

rapidly. Endo spent more than \$10 million in a single quarter in 2006 following the launch of Opana ER and more than \$8 million in a single quarter in 2012 with the launch of a reformulated version. In 2007 and 2008, Endo spent more than \$38 million and nearly \$34 million respectively on promoting its opioids.



#### 4. Janssen and J&J

597. Janssen made and/or disseminated deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval that stated that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, but that concealed contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial

control and approval;

- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus non-opioid pain relievers;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Endorsing and assisting in the distribution of CME's containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- j. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- k. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- l. Using in-person detailing to make deceptive statements to prescribers concerning the use of opioids to treat chronic non-cancer pain.

**a. Janssen's Misrepresentations Concerning Addiction Risk**

598. Janssen misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, stated, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding addiction.”

599. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.” In 2009, the website stated that “pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012.

600. A Janssen unbranded website, *PrescribeResponsibly.com*, stated that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”<sup>221</sup> The website excused addictive behavior as “pseudoaddiction,” “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately the inappropriate behavior ceases.”<sup>222</sup> The website further stated that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.<sup>223</sup> The website, which directly provides screening tools to prescribers for risk assessments,<sup>224</sup> includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.<sup>225</sup>

601. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which described as “myth” that opioids are addictive

---

<sup>221</sup> Keith Candiotti, *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

<sup>222</sup> Howard A. Heit & Douglas L. Gourlay, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberresponsibly.com/articles/before-prescribing-opioids=pseudoaddiction>, (last modified July 2, 2015) (hereinafter “*What a Prescriber Should Know*”).

<sup>223</sup> *Id.*

<sup>224</sup> Risk Assessment Resources, PRESCRIBE RESPONSIBLY, <http://www.prescriberresponsibly.com/risk-assessment-resources> (last accessed August 1, 2018).

<sup>225</sup> *Id.*



and asserted as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”

**Myth: Opioid medications are always addictive.**

**Fact:** Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Until recently, this guide was still available online.

602. Janssen’s website for Duragesic, a transdermal fentanyl patch, included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

603. Janssen promoted Duragesic as improving patients’ functioning and work productivity through an ad campaign that included the following statements: “[w]ork, uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] . . . physical and social functioning.”

604. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any

quality of life claims.<sup>226</sup>

605. As noted above, Janssen sponsored and edited a patient education guide, *Finding Relief: Pain Management for Older Adults*, which stated as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing*, sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function.

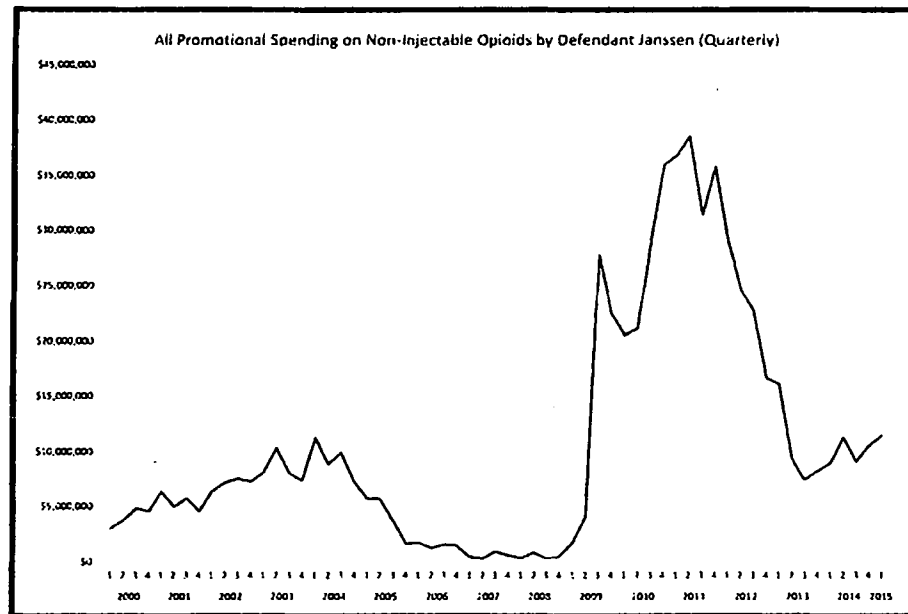
606. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, edited by Janssen personnel, which claimed that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

607. *Finding Relief: Pain Management for Older Adults* listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are constipation and “upset stomach or sleepiness,” which the brochure claims will go away.

608. As shown below, Janssen’s quarterly promotional spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER. In that year, Janssen spent \$142 million to promote its opioids:

---

<sup>226</sup> *Pain Killer, supra*, at 281.



609. Janssen also made numerous representations that minimized the risks and vastly overstated the efficacy of Janssen opioids and otherwise falsely and misleadingly stressed that opioids were appropriate for “chronic pain” generally, rather than only for treatment of pain in the limited circumstances authorized by the FDA. Janssen’s marketing of its own drugs mirrored the sorts of claims it was made about opioids generally. Even in the face of numerous FDA warnings, Janssen stubbornly marketed its products as having “less abuse potential” and as being appropriate for treatment of “chronic pain.”

610. Janssen viewed chronic pain as the real untapped market. Starting in the mid-1990s, at around the same time that Purdue introduced OxyContin CR, Janssen’s promotion of Duragesic shifted from a focus on cancer pain to chronic pain generally and introduced comparisons to oral opioids. The “Duragesic Ad Campaign Overview” timeline noted that as of May 1994 there was a “[s]hift away from limiting consideration to only malignant patients” to “[p]romotion of around-the-clock control highlights benefits of 72 hour efficacy in limiting breakthrough pain associated with oral

medications.” The Duragesic “Journal Advertising Overview” shows that from April 1995 to July 1997, Janssen’s “Core Campaign Journal Ad” for Duragesic used the headline “Why Interrupt These Moments With Oral Opioid Dosing?” and the tagline “Chronic Pain Control That Goes On.”

611. A Duragesic Business Plan for 2001, dated 2000, stated that Duragesic’s “vision” was to be the “first choice of chronic pain patients for around-the clock-therapy.” The Plan noted that “[n]on-malignant market is the growth opportunity,” but stated just below this point that “DURAGESIC data is non-existent.” Another analysis in the same document stated that “opioid acceptance for non-malignant pain” was an opportunity for Duragesic, but that “limited clinical data” was a weakness. Elsewhere in the same plan is the statement “need non-malignant pain data (lower back, OA [osteoarthritis]/RA [rheumatoid arthritis]).”

612. A 2003 “Duragesic Public Relations Activities” PowerPoint identified “[e]xpand in non-malignant pain categories (back pain)” as a “Core Duragesic Brand Strategy” and “[t]arget non-malignant severe chronic pain states (primarily lower back)” as a “2003 PR Objective.”

613. Under “Direct-to-Patient Awareness,” the presentation advocated that Janssen “[u]se broad, unbranded messages and stories about serious chronic back pain to attract potential patients” and “[d]raw potential patients to ‘opt-in’ to branded Duragesic information on Internet.” It further suggested creating a website called [www.chronicbackpain.com](http://www.chronicbackpain.com) to “utilize Internet to engage, capture chronic back pain patients.” The PR plan explained that the “primary emphasis on lower back pain” was because, “[a]long with osteoarthritis,” lower back pain was “identified as key growth opportunity,” but “[u]nlike OA, chronic back pain is not ‘owned’ by any medication or pharmaceutical company.”

614. Janssen sent its sales force bulletins and training materials alerting them to studies of Duragesic for chronic non-cancer pain and used professional file cards and similar materials in marketing that touted these studies.

615. One of the studies was “Evaluation of Long-term Efficacy and Safety of Transdermal Fentanyl in the Treatment of Chronic Noncancer Pain” by Mulligan et al. Janssen advised the sales force that the study’s authors stated that Duragesic provided “stable, sustained, long-term pain

control” even though the study had found that one-third of its subjects did not respond to Duragesic. Janssen explained this fact by stating that it “coincided with Perry Fine’s comments (see editorial) that a process of trial and error is often needed to achieve adequate pain management.” With regards to the study’s reported global efficacy rate of 42%, Janssen advised its sales force that “[a] possible explanation for the low rate of global efficacy is that . . . the results for the global efficacy measurement did not include a ‘moderate’ rating,” an explanation not offered by the study itself. As to the study’s reported withdrawal (drop-out) rate of 43%, Janssen advised its sales force that the study’s authors found “the incidence of AEs [adverse events] and the rate of withdrawal from the trial are relatively high but neither unusual nor unexpected considering the baseline clinical status of the study population.” Janssen further advised its sales force that the fact that withdrawals due to adverse events or insufficient response diminished after six months “may indicate that most of the withdrawals secondary to insufficient response or AEs may be related to improper titration and lack of tolerability to the transient side effects of TDF [transdermal fentanyl, i.e., Duragesic],” again an explanation not found in the study.

616. Canadian health authorities had previously commented to Janssen that the studies it submitted in support of the use of Duragesic for chronic pain, including the Milligan study, involved only patients who were already taking potent opioids before entering the studies. The Canadian authorities further noted that “the treatment of opioid naive patients with transdermal fentanyl for postoperative pain has resulted in deaths due to respiratory depression in the past.” In its reply, Janssen stated, “We acknowledge that the experience in opioid naive non-cancer patients is limited.” No such acknowledgement was made in Janssen’s bulletin to its sales force about the Milligan study. Janssen also did not advise its sales force in the bulletin that the stability of pain control achieved in the study came at the cost of nearly doubling the mean dose of Duragesic over 12 months. A Janssen scientist raised concerns with the Milligan study, sending an email stating she wanted to “reiterate” concerns that had been raised regarding using the Milligan study “to make an argument for efficacy.” She noted that “these studies not [sic] the appropriate design neither the end points to make a case for efficacy.”

Janssen did not disclose these concerns to its sales force. Nor did Janssen disclose that the Milligan study was supported by a grant from the Janssen Research Foundation and that the lead author had received financial support from Janssen.

617. Janssen also provided its sales force with a 1997 study by Simpson et al. entitled “Transdermal Fentanyl as Treatment for Chronic Low Back Pain.” Janssen advised its sales force that the study results suggested “that patients on DURAGESIC treated for chronic low back pain report greater improvement in pain relief and disability than those who received oral opioids” and that “use of Duragesic may be associated with less disability caused by chronic lower back pain.” In professional file cards and other materials used by sales representatives, Janssen likewise cited the Simpson study for its claim that Duragesic “[d]emonstrated effectiveness in chronic back pain with additional patient benefits” and also claimed that “[a]ll patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.”

618. In its September 2004 warning letter to Janssen, the FDA found that the Simpson study was “inadequate to support th[ese] claim[s], because it was an open-label, single-arm trial with no control group” and further stated, “We are not aware of substantial evidence or substantial clinical experience to support th[ese] claim[s].” The FDA found these claims to be “unsubstantiated effectiveness claims,” that they and other misleading claims on the file card were “serious” violations and constituted misbranding, and requested that Janssen “immediately cease dissemination” of these claims and come up with a plan for corrective action.

619. Janssen knew and intended to promote its opioids for the sort of chronic pain relief that was not permitted by the FDA, and the 2004 FDA letter was the third of three letters that the FDA sent Janssen about its marketing claims.

620. In a 2000 letter, the FDA described Duragesic’s poster as recommending use in chronic pain patients. The FDA characterized this ad as the “promotion of unapproved use,” noting that the qualifying limitation that use is approved “in the management of chronic pain in patients who required continuous opioid analgesia for pain that cannot be managed by lesser means” “was placed

near the bottom of the poster in small, inconspicuous type size, misleading and overwhelmed by the more prominent claim of chronic pain at the top of the poster.”

621. In that same letter, the FDA declared as “false and misleading” Janssen’s claim that Duragesic “stops the pain. Not the patient.” The FDA stated, “Janssen’s statement implies that the use of Duragesic is not associated with any impairment of mental or physical abilities. Janssen has not submitted data to substantiate such a claim.”

622. Despite these warnings, Janssen continued to market Duragesic in materially the same way.

623. In or about 2002, Janssen developed another ad campaign for Duragesic. Photos on the four ads depicted the following:

- a. a man (presumably the father of the bride) laughing with the bride with the caption: “This day will be a lifelong memory. I’m glad chronic pain won’t be a part of it.”
- b. two hands kneading a loaf of bread with the caption: “1,360 loaves ... and counting. Work, uninterrupted.”
- c. the torso of a “blue-collar” man holding a bowling ball with the caption: “506 strikes ... and counting. Game, uninterrupted.”
- d. a man holding a packing box with the caption: “Work. Plan. Stand. Sit. Bend. Stretch. Move. Carry.”

624. In the same 2004 warning letter addressing the Simpson study, the FDA found this ad campaign to be “misleading”: “These outcome claims are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic. Janssen has not provided references to support these outcome claims.” The FDA requested that Janssen “immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described above. ... Because the violations described above are serious, we request, further, that your submission include a plan of action to disseminate truthful, nonmisleading, and complete information to the audience(s) that received the violative promotional materials.”

625. In short, Janssen marketed Duragesic in a way to broaden its indications beyond the label. By so doing, it lent its powerful voice to the chorus of those advocating for the expanded use

of powerful opioids (in this case, fentanyl) for chronic pain by minimizing the risks and overstating the benefits. This conduct expanded the use of prescription opioids in general and the use long-lasting opioids in particular.

626. This approach to defining the market and the uses for its products is Janssen's *modus operandi*. In Janssen's 2011 Nucynta Business Plan, among the "Strategies & Executional Drivers" was "Strengthen differentiation through new & compelling Evidence", which included demonstrating "Superior Efficacy vs. Oxy;" "Real World outcomes vs. Oxy;" and "Reduced abuse potential."

627. In Janssen's 2012 Nucynta and Nucynta ER 2012 Business Plan, again, an aspect of the Marketing Strategies associated with "differentiation" was to "Generate data to support . . . Lower abuse potential."

628. Janssen's conduct and its goal – to legitimize and expand the market for opioids to the "lower back pain" sufferer – remained unchanged.

**b. J&J's Activities Through Tasmanian Alkaloids and Noramco.**

629. Sometime in the 1980s, Janssen acquired Tasmanian Alkaloids PTY, LTD ("Tasmanian Alkaloids"). According to a presentation created by Janssen sometime prior to its sale of Noramco, Inc. and Tasmanian Alkaloids, the purpose of Janssen's acquisition was to "secure another piece of the value chain."

630. In the early 1990s, J&J, through Noramco, began discussions with Purdue Pharmaceuticals regarding the anticipated future demand for opioid painkillers, including those opioid painkillers with oxycodone as the primary active ingredient.

631. In or around 1994, Tasmanian Alkaloids began a research project with the purpose of creating a poppy plant with enhanced thebaine content; thebaine is a precursor from which oxycodone and hydrocodone can be produced. The purpose of the project was to meet the "anticipated demand" for oxycodone-based opioids, including Oxycontin.

632. This research project was successful, and in or around 1996, Tasmanian Alkaloids began a program to entice Tasmanian farmers to grow the new poppy, which eventually constituted



the majority of the Tasmanian crop. Unlike traditional opium poppies, these poppies had no morphine, which made the purification process was simpler.

633. In 2000, the individual credited with the discovery or development of the “Tasmanian poppy,” agricultural scientist Anthony J. First, was given the Johnson & Johnson Medal, J&J’s highest award for scientific research and innovation.

634. Tasmanian Alkaloids bought the poppies from farmers and then shipped concentrated poppy products to the United States where Noramco processed the raw materials into oxycodone, hydrocodone, and other opioid products.

635. By 1998, Noramco had begun receiving the highly concentrated thebaine poppy straw from Tasmanian Alkaloids and engaged in discussions and/or business transactions with Purdue to supply oxycodone.

636. As a condition of supplying oxycodone, Noramco requested assurances from Purdue that the latter would be able to manufacture and sell significant quantities of oxycodone-based products.

637. Over the next two decades, Noramco provided active pharmaceutical ingredients, including oxycodone and other thebaine-based products, to several of the Marketing Defendants.

638. A Noramco official would later boast that the “patented, high-thebaine poppy was a transformational technology that enabled the growth of oxycodone.” As described below, Tasmanian Alkaloids and Noramco, together, became world leaders in the supply of oxycodone, and J&J, through those entities, financially benefitted from the epidemic above and beyond the profits from Janssen’s sales of opioid products.

639. A Purdue affiliate, PF Laboratories, was one of the first major customers for Noramco’s product. A Noramco executive wrote to PF Laboratories in October 1998: “Noramco will work with PF Laboratories to secure its entire worldwide requirements. This is not a minor point. As we have discussed, access to raw materials is going to be critical to obtaining security of supply.” The letter is replete with references to Noramco’s intent to expand production to meet Purdue’s needs,

explaining that “[t]he capacity expansions are . . . still on track;” “[t]he Wilmington facility to produce the penultimate and final steps of oxycodone will be completed by year-end[;]” “[t]he engineering for the expansion of our hydrogenation capacity is well underway[;]” and “[t]he facility in Athens [Georgia] will be completed by year-end.”

640. The letter contemplates a “long-term commitment”: “With a long term commitment, Noramco can work to provide even more capacity than in this proposal that will give PF Laboratories the maximum security of supply for its franchise . . . .” In return: “Of course, we need long term commitment from PF Laboratories to be able to provide the support this proposal envisions.” The precise date when Noramco began to supply Purdue, the precise terms of their supply agreement, and the precise amounts of oxycodone actually provided are not currently known.

641. In 2011, the J&J Family of Companies in Australia submitted a document to the Therapeutic Goods Administration, the part of the Australian Government Department of Health responsible for regulating medicines, vaccines, medical devices, and similar products. In that submission, J&J represented:

In 1995, Tasmanian Alkaloids initiated a project to develop a high-thebaine poppy. In sampling the alkaloid content of thousands of plants, one plant was found to have a high content of thebaine and no morphine, and the first commercial crop of these unique poppies was harvested in 1998. The new plant revolutionized thebaine production and today it has up to 80% of the worldwide market for Oxycodone raw materials. Tasmanian Alkaloids is presently the largest manufacturer of active pharmaceutical ingredients in Australia and the largest exporter of codeine and thebaine in the world.

642. It is unknown precisely how much oxycodone was produced by Noramco or the quantities sold to various customers (including the Marketing Defendants). In 2015, at the time when J&J was attempting to sell off Noramco and Tasmanian Alkaloids, J&J prepared a marketing brochure representing that:

- a. the purchaser had the opportunity to “[a]cquire the #1 supplier of Narcotic AOSs in the United States” and “[b]ecome a key supplier to the world’s largest multi-source generics;”
- b. the Noramco portfolio of products, (with net trade sales in 2014), included Oxycodone (\$94 million); hydrocodone (\$52 million); buprenorphine (\$20

million); morphine (\$20 million); codeine (\$18 million); and other products, for a global 2014 sales of \$258 million;

- c. Noramco's U.S. market share of these products in 2014 was as follows: oxycodone (65%); hydrocodone (54%); codeine (60%); and morphine (60%);
- d. "Tasmanian Alkaloids produces over 40% of the world's supply of Narcotic Raw Materials;"
- e. "Tasmanian Alkaloids has the highest content poppies for key alkaloids;" and
- f. Noramco and Tasmanian Alkaloids, located in four locations around the world (Wilmington, Delaware; Athens, Georgia; Tasmania, Australia; and Schaffhausen, Switzerland) had 483 full-time equivalent employees, including 28 employees shared with J&J.

643. This brochure also represented that "Noramco has long-term agreements and/or majority controlled substance share with all 7 of the top US generic companies." The marketing materials represented, as to "typical supply terms:"

- a. Agreements cover multiple controlled substance products (4 or more);
- b. Agreements are for more than 80% of customer's volume; and
- c. Terms are for 3 to 5 years minimum with rolling renewals.

644. The thebaine poppy allowed a dramatic increase in the production of oxycodone, which in turn allowed a dramatic increase in the production, marketing, and sales of oxycodone-based products.

645. As of 2015, roughly sixty-five percent of all oxycodone consumed in the United States was distributed by Noramco.

646. J&J sold Noramco and Tasmanian Alkaloids for \$650 million to a private equity firm in or around 2016.

**c. Janssen's Unbranded Promotion of Opioids and Action in Concert With its Co-Conspirators**

647. As set forth at other places in this Complaint, Janssen made numerous representations that minimized addiction risks and made numerous other related representations (such as advocating

the concept of “pseudo-addiction”) as part of efforts to expand the market for opioids. These included representations in the *Let’s Talk Pain* website, the unbranded website *PrescribeResponsibly.com*, and a patient education guide titled *Finding Relief: Pain Management for Older Adults*. These representations pertained to opioid use generally and were not limited solely to Janssen products. Though these messages were useful for expanding the market for Janssen’s opioids, they were also useful for expanding the market for opioids generally—thus increasing the demand for the oxycodone supplied by Tasmanian Alkaloids and Noramco.

648. In addition, as set forth in other places in the Complaint, Janssen funded Front Groups and KOLs to make this message and thus created an echo chamber that amplified Janssen’s message but in a way that concealed Janssen’s involvement. In total, from 1997 to 2012, Janssen made the following payments:

The American Pain Foundation	\$633,300
The American Academy of Pain Medicine	\$562,674
The American Pain Society	\$1,793,906
The American Geriatrics Society	\$565,626
The Center for Practical Bioethics	\$8000
Joint Commission Resources	\$515,244
(SUB TOTAL)	\$4,078,750.00
Payments to KOLs	\$327,546
TOTAL	\$4,406,296

These included the following amounts paid to the four largest of these groups:

	American Pain Foundation	American Academy of Pain Medicine	American Pain Society	American Geriatrics Society	Joint Commission
1997		\$43,500	\$146,215		
1998		\$14,400	\$480,905		
1999		\$135,140	\$71,595		
2000		\$74,050	\$444,536		
2001		\$66,764	\$158,000		\$16,453
2002		\$43,975	\$111,125		
2003		\$33,000	\$75,285		
2004	\$5,000	\$35,620	\$166,250	\$259,080	
2005	\$5,000	\$21,300	\$19,510	\$126,383	
2006	0	\$13,375	\$35,930	\$1,950	
2007	\$5,000	\$42,050	\$18,200		
2008	\$75,000	\$20,000	\$6,580		
2009	\$45,000	\$5,000	\$8,775		
2010	\$235,300	\$5,000	\$21,000	\$158,209	
2011	\$238,000	\$9,500	\$17,500	\$20,004	\$498,791
2012	\$25,000		\$12,500		

649. The payments to AGS are notable. In 2002 and 2009, AGS came out with the opioid guidelines. AGS did not want money up front from the manufacturers. Janssen made payments to the AGS in the years following the promulgation of its guidelines.

650. As described elsewhere, the AAPM and the APS are entities that were funded by the Marketing Defendants and run in substantial part by some of the KOLs who were paid by the manufacturers in other contexts. In 1996, AAPM and APS issued a “consensus” statement that

endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. In the next four years, Janssen paid about \$1.4 million to those organizations.

651. Because J&J not only sold an opioid product through Janssen but, through Noramco, also supplied APIs to the opioid manufacturing industry, it had profound financial incentives to expand the market for opioid products.

652. As a supplier (through Noramco) of raw materials to other opioid manufacturers, including Purdue, J&J played a unique role in keeping the conspiracy together, as the conspirators included its customers.

653. As described in various places in the Complaint, the conspiracy functioned in part through the numerous actions of Defendants working together to fund or establish Front Groups and to use common KOLs. As but one example, in 2001 the New York Times published an article about the opioid industry. An internal email from Purdue reflects that a Purdue executive had a conversation with one of the KOLs used by Janssen and Purdue. "Russ [Portenoy] said that Janssen called and has called others to try to help deal with this media blitz and protect the pain movement." This is the conspiracy in action.

654. At no point after Purdue pleaded guilty in 2007 to a federal felony related to marketing OxyContin did Janssen ever inform Dr. Portenoy that it wanted to cease involvement with him so long as remained involved with Purdue.

655. When issues began to arise about abuse and diversion of Purdue's OxyContin, an internal Janssen email stated, "It was not [Janssen's] policy to advance language that would attack a competitor's product." The email stresses the "need to have enough foresight to look towards the future of pain management." In other words, what is bad for Purdue is bad for Janssen. This is, of course, in addition to J&J's interest in Purdue as a customer for Noramco APIs.

656. At about the same time, Purdue sent a memorandum to its "Entire Field Force" instructing them about the agreement that Purdue and Janssen reached to not disparage the other's products or to raise competitors' drug diversion problems:

This past week, we received a complaint from Janssen's president indicating that our representatives are discussing various ways in which the Duragesic patch is abused and diverted. . . . While abuse and diversion reports for OxyContin, Duragesic, and other pharmaceutical preparations may be part of the printed and electronic press, this knowledge or information should not be discussed or used as part of the promotion of OxyContin. . . . Janssen Pharmaceuticals and Purdue have agreed that should either company have representatives who promote product out of label **or out of policy**, the name of the representative will be provided to the other company for investigation and disciplinary action if necessary. . . . I trust that this memo is clear.

(emphasis supplied).

657. KOLs paid by Janssen encouraged extensive use of opioids to treat chronic pain.

658. The 1997 APS/AAPM Consensus statement was drafted by Drs. Haddox, Portenoy, and Joransson, all paid by Janssen.

659. A Purdue email from 2004 noted that NPEC, an organization supported by Janssen, used "the same speakers [who] spoke for us at regional and national meetings." Dr. Portenoy was cochair of the NPEC, which, according to an internal Janssen document, was used to assist in marketing Duragesic.

#### **d. FDA Warnings about Duragesic**

660. Duragesic is approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

661. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." This letter detailed numerous ways in which Janssen's marketing was misleading.

662. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated

effectiveness claims for Duragesic,” including “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.”

663. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor. The advisory noted that the FDA had been “examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients and physicians might be unaware of the risks” of using the drug.

#### **e. Janssen and J&J’s Losses in Recent Litigation**

664. In 2019, in the MDL proceeding styled *In re: National Prescription Opiate Litigation*, MDL 2804 (N.D. Ohio), Janssen and J&J lost summary judgment motions on the issue of their liability.<sup>227</sup>

665. Following a bench trial over its role in creating and sustaining the opioid epidemic, an Oklahoma court found that Janssen’s opioid marketing was “false, deceptive and misleading” and entered judgment against Janssen and J&J.<sup>228</sup> The court ordered Janssen and J&J to pay the state \$572 million.<sup>229</sup>

666. The judge found that the state had proven that J&J created a public nuisance by exaggerating the benefits of narcotic painkillers and minimizing their addiction risks. The court also found that “the public in general are currently experiencing an opioid crisis and epidemic.”<sup>230</sup>

667. According to the court, J&J’s marketing and promotion activities included, among other things, their sales representatives providing education, literature they funded in medical journals

<sup>227</sup> Opinion and Order Denying Janssen’s Motion for Summary Judgment, *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4194293, at \*2–3 (N.D. Ohio Sept. 4, 2019); Opinion and Order Re: Preemption, *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4178591 (N.D. Ohio Sept. 3, 2019); Opinion and Order Regarding Defendants’ Summary Judgment Motions on Causation, *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4178617 (N.D. Ohio Sept. 3, 2019).

<sup>228</sup> No. CJ-2017-816, at ¶ 44 (Cleveland Cnty. Dist. Ct., Okla. Aug. 26, 2019), <https://www.courthousenews.com/wp-content/uploads/2019/08/OklaJJOpioid-VERDICT.pdf>

<sup>229</sup> Jan Hoffman, *Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial*, N.Y. TIMES (Aug. 26, 2019), <https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html>; see also Judgment After Non-Jury Trial, Aug. 26, 2019, Case No. CJ-2017-816 (Okla. Cleveland Cnty. Dist. Ct.) (“Okla. Judgment”).

<sup>230</sup> Okla. Judgment, Findings of Fact, ¶1.



and publications, materials from professional societies/patient advocacy groups, continuing medical education they funded, unbranded marketing materials, and paid speakers.<sup>231</sup>

668. The key messages in this marketing strategy included using the term “pseudoaddiction” to promote the concept that chronic pain was undertreated and that the solution to this problem was increasing opioid use.<sup>232</sup> Sales representatives did not, however, receive training regarding “pill mill” red flags, such as “pain clinics with patients lined up out the door or patients passed out in the waiting room.”<sup>233</sup>

669. According to the court, J&J, through its wholly owned subsidiaries, Tasmanian Alkaloids and Noramco, supplied opioid manufacturers with APIs from the 1990s until at least 2016. Tasmanian Alkaloids “cultivated and processed opium poppy plants to manufacture narcotic raw materials that were imported into the U.S. to be processed and made into APIs for manufacturing opioids.” Noramco imported the raw materials, processed these materials into APIs, and sold them to opioid manufacturers in the United States.<sup>234</sup>

670. According to the court, drug manufacturers in the United States, including Purdue and Teva, were supplied the following opioid APIs through J&J operations: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.<sup>235</sup> Noramco sold its APIs, including oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone, through long-term agreements with all seven of the top U.S. generic manufacturing companies.<sup>236</sup>

671. According to the court, in 2015, J&J’s operations, comprised of Noramco and Tasmanian Alkaloids and called “Noramco World Wide Narcotics Franchise,” held the distinction of being “the #1 supplier of Narcotic APIs in the United States, the world’s largest market.”<sup>237</sup> “Noramco

---

<sup>231</sup> *Id.* ¶19.

<sup>232</sup> *Id.* ¶20.

<sup>233</sup> *Id.* ¶33.

<sup>234</sup> *Id.* ¶6.

<sup>235</sup> *Id.* ¶7.

<sup>236</sup> *Id.* ¶14.

<sup>237</sup> *Id.* ¶8.

grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States.”<sup>238</sup>

## 5. Teva

672. Teva made and/or disseminated untrue, false, and deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Teva’s potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Teva’s rapid-onset opioids;
- h. Directing its marketing of Teva’s rapid-onset opioids to a wide range of doctors serving chronic pain patients, including general practitioners, neurologists, sports medicine specialists, and workers’ compensation programs; and
- i. Making deceptive statements concerning the use of Teva’s opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers’ bureau events, when such uses were unapproved and unsafe.

---

<sup>238</sup> *Id.* ¶15.

**a. Teva's Marketing in New York**

673. Teva has promoted, advertised, and sold opioids nationwide and in New York, including Actiq (fentanyl citrate), Fentora (fentanyl buccal), oxymorphone, and hydrocodone.

674. From 2009 to June 2013, Teva reported its payments to physicians for speaking, consulting, educational items, meals, research, and travel as part of its five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services in connection with a 2008 guilty plea. During this time, payments made to New York physicians totaled \$5,975,328.<sup>239</sup>

675. Teva and/or its corporate affiliates held prescription drug manufacturer, distributor, and wholesaler licenses under New York law during all relevant times.

676. Teva ensured nationwide marketing consistency through sales representative training. Teva relied on its sales representatives to convey marketing messages and materials to prescribers in targeted, in-person settings. Teva directed and monitored all of its sales representatives through detailed action plans, training, and review of sales representatives' notes from visits in order to ensure the desired messages were being delivered to prescribers. On information and belief, the marketing strategies, scripted messages, and materials Teva salespeople carried out in New York were consistent with Teva's nationwide campaign.

677. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon (along with Purdue) sponsored APF's *Treatment Options: A Guide for People Living with Pain*, which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft; falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed;" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

---

<sup>239</sup> See ProPublica, *Dollars for Docs: How Industry Dollars Reach Your Doctors*, <https://projects.propublica.org/d4d-archive/companies/cephalon>.

678. Cephalon, Endo, and Purdue sponsored FSMB's *Responsible Opioid Prescribing*, written by Dr. Scott Fishman, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, all of which are signs of genuine addiction, are really signs of "pseudoaddiction," which is a false concept.

679. APF published a guide sponsored by Cephalon and Purdue, *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in 2007 alone. This guide contains multiple misrepresentations regarding opioid use that are discussed *supra*.

680. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape and which disseminated false and misleading information to physicians across the country.

681. A 2003 Cephalon-sponsored CME titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, promoted the false narrative that opioid treatment for chronic pain would not lead to addiction:

[C]hronic pain is often undertreated, particularly in the non-cancer patient population. ... The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.<sup>240</sup>

682. For its opioid, Actiq, Cephalon also engaged in direct marketing that contravened the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and only by oncologists and pain management doctors experienced in treating cancer pain.

683. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation, *Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough*

<sup>240</sup> Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803> (last accessed July 27, 2017).

*pain: Interim safety results.* The presentation's agenda description stated, "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purported to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promised to show that the "[i]nterim results of this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain]." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

684. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape from September 28, 2007 until December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

685. Another Cephalon-sponsored CME presentation, *Breakthrough Pain: Treatment Rationale with Opioids*, was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He described the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."<sup>241</sup> The doctor listed fentanyl as one of the most effective opioids available for treating breakthrough pain and described its use as an expected and normal part of the pain management process.<sup>242</sup> Nowhere in the CME was cancer or cancer-related pain mentioned, despite the FDA's restrictions.

686. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related

---

<sup>241</sup> Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last accessed August 1, 2018).

<sup>242</sup> *Id.*

has limited utility” and recommended Actiq and Fentora for patients with chronic pain. This CME is still available online.

687. Another CME, *Responsible Opioid Prescribing*, was sponsored by Purdue, Endo and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman. In all, more than 163,000 copies were distributed nationally.

688. To expand the use of its branded fentanyl products, Cephalon sponsored the 2007 publication of an article, “Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate”<sup>243</sup> in the *Journal of Pain Medicine*. The article’s authors (including Dr. Webster) stated that the “OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

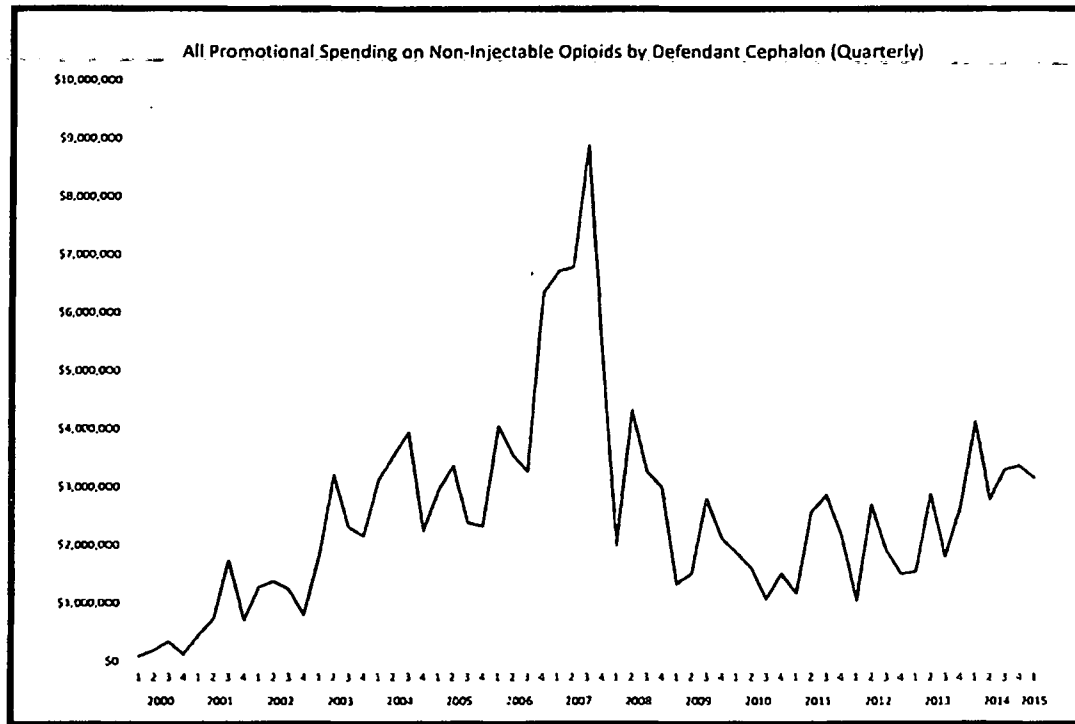
In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.<sup>244</sup>

689. Cephalon’s quarterly marketing spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for that entire year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007:

---

<sup>243</sup> Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

<sup>244</sup> *Id.*



690. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”<sup>245</sup> Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.<sup>246</sup> Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”<sup>247</sup>

<sup>245</sup> Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.  
<sup>246</sup> John Carreyrou, *Narcotic ‘Lollipop’ Becomes Big Seller Despite FDA Curbs*, THE WALL STREET JOURNAL (Nov. 3, 2006), <https://www.wsj.com/articles/SB116252463810112292>.  
<sup>247</sup> *Id.*

**b. Teva and Cephalon Fraudulently Marketed Actiq.**

**i. Approval and Marketing of Actiq**

691. The FDA granted a restricted approval for Actiq pursuant to 21 C.F.R. § 314.20, which allows the FDA to approve drugs with restrictions on use and marketing “as are needed to assure safe use of the drug product.” The Risk Management Authorization (“RMA”) developed in conjunction with FDA approval for Actiq required ensuring that it was used “solely” to treat breakthrough pain in opioid-tolerant cancer patients. The RMA also required production of educational materials for providers that reinforced key safety messages and promoted proper patient-selection messages. The RMA also suggested there would be a salesforce of “Oncology Sales Specialists” to implement the RMA, including limiting Actiq’s promotion to the approved indication of cancer use, discouraging off-label use, and spreading the message of the serious consequences of violating the policy. The RMA also included a commitment to catching and stopping improper use through surveillance and monitoring for improper prescriptions and intervention when problems were discovered.

692. With these restrictions, the FDA thought it could protect public health by controlling and containing use of Actiq to providers treating metastatic cancer patients.

693. Actiq’s manufacturer knew, however, that even if it was subject to the FDA’s restrictions, physicians were not limited to the approved indication. Teva exploited that loophole and subverted the RMA commitment in three ways: (1) by wooing physicians prescribing off-label; (2) by sending its sales force to visit physicians who were prescribing off-label; and (3) by providing physicians and patients with misleading information on Actiq’s risks and benefits, often through channels that circumvented FDA scrutiny.

694. The result was that Cephalon ran a massive uncontrolled experiment to see what happened when non-cancer patients used rapid-release fentanyl.

695. The experiment was conducted on thousands of the very patients it had pledged to protect, patients for whom the FDA had determined that Actiq was too risky. Public health and individual patients suffered the consequences.



**ii. Actiq Marketing to Doctors**

696. Teva paid for many of the top opioid prescribers in the U.S. to travel to conferences at top hotels, like the Ritz Carlton on Amelia Island, Florida.

697. Teva tracked which of its well-paid speakers helped them sell Actiq. For example, in 2003, Teva paid Dr. Steven Simon an honorarium of \$1,500 per conference, plus travel expenses, to present at 20 of its 21 conferences. He frequently presented slides on use of opioids, including Actiq, for chronic back pain and for arthritis.

698. After his presentation to 48 physicians at the Four Seasons in Carlsbad, California, Cephalon's agents circulated a glowing review to Teva's top managers for Actiq, touting Dr. Simon's post-lecture efforts to pitch Actiq to other doctors through "peer-to-peer" detailing (i.e., selling):

Steve Simon is fantastic. He is very good with the attendees at dinner during free time and in the meeting room. He really takes time to "peer-to-peer detail" the attendees. He is a real jewel. During his presentation, he does spend quite a bit of time on the non-pharmacological treatments for OAR/A which on the surface may seem off-strategy. My feeling is that the time he spends on "other" treatments actually "sets" up his strong ACTIQ endorsement by building credibility. Unlike Andrea Cheville who tends to over-endorse ACTIQ, he builds credibility as a "well-rounded" pain doc who has found a place for ACTIQ in his every day practice and I think this message resonates. He does want to change a few things - but I am trying to discourage this if you are OK with that. I would like to see him "not to change a single thing".

699. Teva's regional sales managers and senior managers, including those responsible for insuring compliance with the Actiq RMA, attended these conferences. However, rather than monitoring doctors for off-label or contraindicated uses, these sales managers identified doctors prescribing off-label so that they could provide them with more reasons to prescribe off-label.

700. Materials prepared for conferences and meetings, which promoted Actiq for migraines, back pain, and arthritis, were withheld from the FDA under the theory that they were not promotional. That attendees were selected by sales staff and that Cephalon's agents thought the

purpose was to sell Actiq shows otherwise. The meetings were, in fact, promotional and were a key part of the sales strategy for Actiq.

701. Doctors attending conferences returned to their states where they prescribed Actiq for off-label uses.

702. For example, a Virginia Beach rheumatologist attended the August 2003 MidAtlantic Conference at the Ritz-Carlton Reynolds Plantation, in Greensboro, Georgia. There, he listened to presentations from Dr. Simon on Actiq's use for chronic back pain and from another doctor on Actiq's use for migraine headaches. He also attended a roundtable where doctors discussed Actiq's use for fibromyalgia, migraines, and chronic pain. After the conference, the doctor continued to aggressively prescribe Actiq (and other opioids) to patients suffering from fibromyalgia, chronic pain, and headaches. From December 2003 to August 2008, five of his patients died of narcotics overdoses. Others were hospitalized for drug-related conditions, including two of his Actiq patients, both of whom were sent to psychiatric treatment and drug detoxification in February 2004. During this time, Teva rated the doctor a top prescriber of Actiq (8 out of a maximum of 10), conducted scores of sales visits to him, and only ceased sales visits when the Virginia Board of Medicine summarily suspended the doctor's license in August 2008. Teva also circulated at least four internal lists flagging the doctor as a "repeat off-label Actiq prescriber." Despite these internal flags, Cephalon's sales staff continued to regularly visit the doctor to push Actiq and Fentora sales up until the date the Board of Medicine suspended his license.

703. Cephalon and Teva made over 500,000 sales visits to healthcare providers from 1999 to 2017 for Actiq and Fentora. Most of these providers were not treating cancer patients; they were providers in specialties like primary care, family medicine, physical medicine, and neurology. Most of the prescriptions these providers wrote were not to treat cancer pain.

704. The following chart illustrates sales calls for Actiq during the first seven months of 2004. It illustrates clearly that Cephalon and Teva targeted doctors with generalized practices rather than practices more closely aligned with the approved labeling and the RMA. Over 50% of the targeted

doctors practiced family or internal medicine and over a quarter of the calls on which Actiq was discussed were with these sorts of practitioners:

Actiq Physician Universe Call Activity 2004 YTD						
Specialty	Total Number of Physicians Targeted		Physicians Called On During 2004		Total Number of Actiq Calls During 2004 *	
	N	%	N	%	N	%
Family Practice (FP)	8943	26%	2247	25%	7534	15%
Internal Medicine (IM)	7840	26%	1824	23%	6200	12%
Oncology-Medical (ON)	1696	5%	691	41%	1970	4%
Anesthesiology (AN)	1656	5%	1270	77%	9329	18%
Physical Medicine (PM)	1593	5%	1111	70%	7300	14%
Neurology (N)	1060	3%	706	67%	3809	7%
General Practice (GP)	931	3%	281	30%	1046	2%
Hematology Oncology (HO)	799	3%	292	37%	888	2%
Anesthesiology-Pain Management (APM)	786	3%	634	81%	5148	10%
All Other Oncology	781	3%	298	38%	969	2%
Rheumatology (RH)	659	2%	333	51%	1504	3%
All Other Specialties	3265	12%	1085	29%	5832	11%
Total	30509	100%	10781	36%	51547	100%

\* The total number of calls may be higher than the number physicians called upon because a physician may be called on multiple times

705. Sales strategies for Actiq focused on top prescribers to drive sales up. For example, a 2002 email from a salesperson in the southeast said that 14 physicians deemed “product champions” accounted for 30% of Actiq sales in the region, prescribing 162,527 lozenges in just 6 months.

706. A high-performing Florida salesperson described her interactions with a high prescribing doctor: “[i]f I knew that this physician was in town and practicing medicine, I would’ve been in there three times a week pushing him to write more Actiq.” It was later determined that doctor should be removed from the Actiq prescriber target list after he fled the country in the face of a DEA investigation.

### iii. Actiq Marketing to Patients

707. Teva targeted new non-cancer patients by distributing coupons good for six free Actiq lozenges through doctors treating non-cancer patients.

708. The coupons worked. The Actiq business plan for 2000 described coupons as “a remarkably effective promotional tool that fuels prescription growth.” The use of coupons was expanded.

709. By 2005 and 2006, 6,000 to 9,000 coupons per month for Actiq were being distributed nationwide, including coupons for Actiq’s highest doses, 1200 mcg and 1600 mcg.

710. As a result of Actiq marketing efforts, the numbers of Actiq prescriptions rose from 10,000 in the first quarter of 2001 to 90,000 in the last quarter of 2003. Revenue soared too, rising from \$15 million in 2000 to \$600 million a year in 2006.

711. The risk of addiction to Actiq was downplayed. From 2000 to approximately 2003, Actiq salespeople told patients they would not get addicted to Actiq if they followed their physician’s instructions. The sort of false assurances they provided are illustrated by the following document:

**Will I get addicted to this medicine?**

You will not get addicted to Actiq. A common misconception is that people with cancer who are taking strong pain-relieving medicines will become addicted. This is not true. If you follow the instructions that you received from your healthcare professional about taking your pain medicines, these medicines will not become addictive.

What does happen when you take pain-relieving medicines, like Actiq, is that your body becomes dependent on the medicine. This means that if you suddenly stopped taking the medicine, you would experience unpleasant side effects, often referred to as “withdrawal” effects. To prevent this from happening, if you no longer need to take Actiq your doctor or nurse will gradually decrease your dose so that you don’t have these side effects of withdrawal.

712. From 2002 to 2006, Actiq salespeople were trained to tell physicians asking about drug abuse that a “comprehensive evaluation of the abuse potential of ACTIQ was performed prior to FDA approval” and that Cephalon’s risk management program could reduce Actiq’s risk of abuse and diversion. Of course, this message was not supported by clinical trials – there had been no clinical study of Actiq’s abuse potential.

**iv. Auditors Cannot Stop Off-Label Marketing**

713. In 2003, an auditor concluded that the risk management commitments to monitor and prevent off-label prescribing made to the FDA for approval of Actiq were not being met. Rather than change its practices, Cephalon fired the auditor, and the FDA was told that the auditor misunderstood.

714. In 2004, the FDA tried to stop off-label marketing of Actiq. In a June 2004 telephone call, the FDA director responsible for narcotics demanded that “staggering off-label use and increasing reports of diversion, misuse, and unintended pediatric use of Actiq” be addressed. The FDA demanded information about off-label prescriptions: “any and all information that you are aware of related to non-compliance with the risk management program for the product by sales representatives . . . prescribers, dispensers, or patients.”

715. Instead of complying, in July 2004 Cephalon produced misleading information about what it knew of off-label use of Actiq. The company’s internal “chart audit” data revealing off-label use of Actiq was widespread, amounting to 87–92% of the 700,000 Actiq prescriptions made to date. The FDA was told, “We do not track the number of representatives that learn of a physician prescribing off label.” So, even though the RMA for Actiq pledged to monitor physicians for off-label use, in order to willfully remain blind, salespeople were not asked to report physicians prescribing off-label.

716. By August 2004, the FDA realized that it had been deceived and that the training for and targeting of Actiq marketing was the opposite of what had been pledged in the RMA. Instead, they “appear to encourage the off-label use rather than discourage it.” The FDA also connected the off-label prescribing to public health harms, stating that the off-label prescribing “was illegal and, especially with a drug with a risk profile like Actiq, raises significant public health concerns.”

717. The FDA also gave specific advice about sales visits: sales visits should cease once it was learned that a provider was not treating cancer patients and the sales force should stop targeting non-compliant doctors for sales visits under the guise of educating those doctors about proper use.

718. The marketing practices for Actiq did not change after the 2004 meeting with the FDA. Regional sales managers continued to select conference attendees. Conferences continued to feature roundtables discussing how to use Actiq off-label, including for migraines, back pain, chronic non-cancer pain, abdominal pain, kidney pain, arthritis, and neuropathy, as well as paid speakers and slideshows on Actiq for “Treatment of Acute & Chronic Pain.” Sales calls were targeted toward (a) proven prescribers of short- and long-acting opioids; (b) not a surgeon or dentist; or (c) any physician who prescribes Fentora.

**v. 2008 Actiq Settlements**

719. In September 2008, four lawsuits alleging illegal off-label marketing of Actiq and two other non-opioids products from 2001 to 2006 resulted in settlements and fines totaling \$425 million. The lawsuits also resulted in Cephalon’s guilty plea for off-label marketing of Actiq and a corporate integrity agreement with the Office of the Inspector General of HHS to prevent further off-label marketing.

**c. Cephalon Fraudulently Marketed Fentora.**

720. Cephalon was undeterred from changing its aggressive sales techniques. Instead, these tactics shifted to a new rapid release product for cancer pain treatment: Fentora.

721. On a 2007 earnings call Cephalon’s marketing director described the primary target audience for Fentora sales visits were 2,000 “high prescribing opioid physicians who were responsible for 80% of Actiq prescriptions.” The next tier of targets was “high prescribers of opioids but who have not historically prescribed Actiq.” There was no mention of limiting sales to prescribers treating cancer patients.

722. Q&As for Fentora’s salespeople affirmatively told them not to report or flag doctors known to prescribe Fentora off-label for the wrong conditions. Senior managers signed off on the following Q&A used from December 2007 to March 2008:

<p style="text-align: center;"><u>COMPLIANCE:</u></p> <p><b><u>Do compliance officials want us to find/ report physicians who are writing FENTORA off- label?</u></b></p> <p>No</p>
---

(March 2008 Question and Answer for salespeople)

723. A February 2008 internal audit showed no process to “monitor call universes for appropriate prescribers.”

724. It should come as no surprise that the targeting practices for Fentora were also successful. Prescriptions increased from 14,600 in 2006 to nearly 91,000 in 2007. Only a small percentage of these were properly written to cancer patients: 14% in 2006; 16-19% in 2007; 17-21% in 2008.

725. By September 2007, the FDA realized that Cephalon’s risk mitigation plan for Fentora would not actually reduce risks associated with Fentora and issued a Public Health Advisory. The FDA’s warnings continued, but so did Cephalon’s off-label marketing.

726. From 2006 to 2015, Cephalon paid speakers, many of whom were top prescribers, \$9 million to speak about Fentora. Speaking engagements occurred not only at medical offices, but also at bars and restaurants (frequently steakhouses). Attendees received free meals and drinks, and speakers were paid honoraria and travel expenses. Hundreds of doctors repeatedly attended the same presentations – some going to the same presentation more than 30 times – suggesting an interest more in the substance of the meal than in the substance of the presentation. Medical office “practice managers” who could help get prescribers in their offices to write Fentora prescriptions or get insurance companies to pay for Fentora were also invited to steakhouse presentations around the country.

727. Honoraria were paid to speakers even if nobody other than sales representatives attended, which occurred on 276 occasions; speakers were paid a total of \$395,600 in honoraria for such “presentations.”

**d. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora.**

728. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid-tolerant had been prescribed Fentora and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, the FDA specifically denied Cephalon’s 2008 application

to broaden Fentora's indication to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

729. Flagrantly disregarding the FDA's refusal to broaden Fentora's indication, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora. The warning letter described a Fentora internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

730. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

**e. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses.**

731. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions in the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs, and funded CMEs to promote off-label uses.

732. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.



**f. Teva Loses Summary Judgment Motions in the MDL.**

733. In 2019, in the MDL proceeding styled *In re: National Prescription Opiate Litigation*, MDL-2804 (N.D. Ohio), Teva lost summary judgment motions.<sup>248</sup>

**6. Actavis**

734. Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

**a. Marketing of Kadian and Brand Name Products**

735. The Actavis parent company bought the brand-name opioid Kadian in 2008 and actively promoted it through early 2013. A Kadian prescriber guide deceptively represented that Kadian is more difficult to abuse and less addictive than other opioids. Although full of disclaimers that Actavis has not done any studies on the topic and that the guide is “only intended to assist you in forming your own conclusion,” the guide included the following misleading statements: 1) “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine

<sup>248</sup> Opinion and Order Re: Preemption, *In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4178591, at \*10–11, (N.D. Ohio Sept. 3, 2019) (rejecting joint motion, and also rejecting Teva’s “separate motion,” in which “Teva argued that none of Plaintiffs’ experts identified any false statements by them, and assert that neither Teva nor Cephalon should be held responsible for statements made by third parties—such as organizations that Plaintiffs label as front groups”); Opinion and Order Regarding Defendants’ Summary Judgment Motions on Causation, *In re Nat'l Prescription Opiate Litig.*, No. 17-md-2804, 2019 WL 4178617 (N.D. Ohio Sept. 3, 2019).

sulfate for intravenous use by illicit users;” and 2) “KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action;” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine;” “Long duration of action;” and “Minimal fluctuations in peak to trough plasma levels of morphine at steady state.”

736. Actavis received a warning letter from the FDA for circulating a brochure to patients for Kadian representing that pain “can keep you from enjoying life” and “[i]f left untreated, pain can place stress on your body and your mental health. . . .” The FDA found that these representations constituted unsubstantiated claims of effectiveness, as it was “not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviated pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient’s work, physical and mental functioning, daily activities, or the enjoyment of life.”

737. Allergan told patients whose bodies became “tolerant” at their current dose that “[t]his is not addiction,” but rather indicated that a “dose adjustment” was required.

738. In 2010, FDA observed that Actavis’s promotional materials for its Kadian were misleading and “particularly concerning considering the serious and potentially fatal risks associated with the drug.”

739. Nathalie Leitch, head of Actavis’s brand name marketing, in an email to CEO Douglas Boothe on August 26, 2011, stated that an upcoming direct mail and email marketing campaign’s “[m]ain messages . . . are long history of safe and efficacious [sic] use, favorable formulary position and co-pay program.” In the very same email, Leitch concedes that:

We have looked at speakers programs and every derivative thereof and have made the decision not to pursue. Legal and regulatory have been strongly opposed plus the cost-benefit very uncertain *given the complete lack of clinical data for Kadian.*” (emphasis added).

#### **b. Marketing of Generic Products**

740. Before its acquisition by Watson in 2012, Actavis produced twelve different generic opioids including some of the most abused and diverted opioids such as generic OxyContin

(oxycodone I hydrochloride tablet), generic Opana ER (oxymorphone tablet), and generic Duragesic (a transdermal fentanyl patch).

741. Allergan had a sophisticated and well-developed generic marketing program headed by Jinping McCormick, "Director of Generic Marketing." When she was director, Actavis marketed oxycodone immediate-release tablets, oxycodone extended-release tablets (generic OxyContin), fentanyl patches, oxymorphone extended-release (generic Opana ER), and morphine sulfate extended release (generic Kadian). Indeed, Ms. McCormick was tasked with growing generic sales from \$477 million to \$535 million from 2010 to 2011. Her compensation was directly tied to maximizing generic drug sales including generic opioids.

742. Allergan sold both brand-name and generic opioids, and the generic marketing team led by McCormick worked closely with the brand-name marketing team and its sales force. That sales force was provided with specific targets for the drugs it promoted, i.e., "1306 Kadian prescriptions per day" with "the main messages [being] long history of safe and efficacious use, favorable formulary position and co-pay program." This target was set despite a reference in the same email that there was "complete lack of clinical data for Kadian."

743. Allergan's sales force reached out to physicians regarding generic opioids for the sole purpose of maximizing sales. A sales force of about 48 representatives promoted generic Kadian and oxymorphone across most of U.S. through 2012.

744. Allergan used the same sales representatives that marketed its brand-name drugs, including Kadian, to market its generic opioids, including generic Kadian, directly to physicians. These were the same sales representatives that had already been trained with false messaging regarding branded Kadian and opioids generally. McCormick even suggested a "contest" and "bonus plan" for those sales representatives that sold the most oxymorphone ER. The sales representatives' compensation was directly tied to their ability to maximize sales of generic opioids.

745. In addition to using their Kadian sales representatives to promote generic opioids, Allergan employed a wide variety of other marketing tools that contributed to its flooding of the

market with generic opioids. For example, Allergan placed advertisements that omitted the full extent of the risks of the generic opioids in various medical publications. Allergan also misleadingly marketed fentanyl at high doses by saying nothing about the risk of addiction or overdose with such doses. Allergan worked with physician-based telemarketing companies to target high-prescribing physicians with its Kadian messaging.

746. Allergan also marketed its generic opioids through joint marketing plans with distributors like McKesson, for example, on oxymorphone. While the oxymorphone “sell sheet” stated that the drug could only be used for “continuous around-the-clock opioid treatment *for an extended period of time*,” the sell sheet was false and misleading because it stated nothing about the dangers of addiction associated with taking opioids long-term. Indeed, in one email discussing the advertisement, Ms. McCormick asked McKesson whether the requirement to include safety information in a fax blast would be different if they omitted the Actavis logo, suggesting that including the safety information was not a high priority for the generics marketing department.

747. Allergan also promoted its generic opioid drugs by implementing strategic points /rebate plans whereby their customers received points and rebates as high as 15% for selling their generic drugs under what was called a “Choice program;” opioid products were associated with higher amounts of points. It implemented pricing and incentive programs with customers and offered store discounts through its suppliers.

748. These strategies appear to have paid off: Actavis was the second largest labeler in New York from 2006 to 2014, commanding approximately 22% of the opioid market.

## **7. Mallinckrodt**

749. Mallinckrodt made and/or disseminated deceptive statements and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Creating and promoting publications that misrepresented and trivialized the risks of addiction;
- b. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

- c. Making deceptive statements about pseudoaddiction.

### 8. Practice Fusion

750. Practice Fusion made and/or disseminated deceptive statements and concealed materials facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. Developing clinical practice software that prompted doctors to consider Purdue's opioids for their patients by suggesting that doctors focus on assessing and treating a patient's pain symptoms and providing the doctor with a list of potential care plan treatment options, including opioids;
- b. Developing clinical practice software that omitted recommendations from the CDC's Guideline or recommendations provided by the *NEJM*;
- c. Developing clinical practice software that advocated for the use of Purdue's extended-release opioid products for patients with less than severe pain; disregarded whether the patient's pain could be adequately treated by non-opioid products; listed Purdue's extended-release opioid products for patients who had never before received opioid therapy; and recommended Purdue's extended-release opioids as options for patients without chronic pain if they had any other acute pain complaints within the prior three months.

### 9. The Sales Representative Defendants

751. The Sales Representative Defendants knew or should have known of the dangers associated with opioids, including but not limited to the addiction, abuse, and diversion that was occurring in New York.

752. The Sales Representative Defendants knew or should have known that opioids were highly susceptible to addiction, misuse, abuse, and diversion; that opioid addiction, misuse, abuse, and diversion bore a direct relationship to the amount and volume of opioids being prescribed; and that opioids were being misused, abused, and diverted across the country and within New York.

753. The Sales Representative Defendants knew or should have known that opioids were dangerous, highly addictive, and highly susceptible to abuse and diversion, yet knowingly or negligently provided false or misleading information to prescribers within New York concerning the relative safety of opioids and the risk of addiction, abuse and diversion.

754. Upon information and belief, the Sales Representative Defendants purposefully or negligently caused the flooding of communities across New York with highly dangerous and addictive opioids all the while knowing that these drugs were being misused, abused and diverted.

755. The Sales Representative Defendants knew or should have known that opioid addiction, abuse, and diversion and their related consequences would injure and damage communities across the country, including those in New York.

756. The escalating number of prescriptions for these highly addictive drugs and the sheer volume of pills flowing into New York should have further alerted the Sales Representative Defendants that their marketing practices were fueling increased addiction, abuse and diversion and that legitimate medical purposes were not being served.

757. The Sales Representative Defendants had a financial incentive to knowingly provide false information to prescribers within New York because their pay and continued employment depending on the volume of sales within their territories. Upon information and belief, the Sales Representative Defendants received extremely lucrative bonuses, trips, and other items of value as a result of their success in pushing opioids into the communities of New York.

758. The Sales Representative Defendants were trained to evade physicians' questions regarding opioids' addictiveness and likelihood of addiction, misuse, abuse, and diversion and to misrepresent and conceal facts relating to opioid safety.

759. The Sales Representative Defendants knew or should have known their marketing and the information they and their sales team provided was a substantial factor in physicians, patients, and others prescribing, purchasing, or using opioids in New York.

## **VI. FRAUDULENT MARKETING CONDUCT BY CVS**

### **A. CVS's Work with Purdue**

760. As early as 2001, CVS worked with Purdue and its unbranded marketing arm, Partners Against Pain ("PAP"), to "fight back" against allegations (later proved to be true) that Purdue's OxyContin was being abused at alarming rates. Purdue and its partners, including CVS, used Purdue's

PAP website to claim that the risk of addiction associated with OxyContin was very small.

761. CVS also worked with Purdue to ensure that CVS pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis of Purdue's 2007 criminal guilty plea and \$600 million fine for misleading regulators, doctors, and patients about OxyContin's risk of addiction and potential for abuse.

762. Purdue's and CVS's tactics included (1) distributing what an internal Purdue memo describes as "our . . . Brochure" purporting to teach pharmacists how to identify fraudulent prescriptions; (2) requiring new CVS hires to view what Purdue describes as "our written CE [continuing education] programs;" and (3) planning to co-host additional CE programs to indoctrinate pharmacists and other health professionals with Purdue's misrepresentations concerning opioids.

763. The Purdue memo, reproduced below, also reveals that these tactics were supported by CVS leadership, including its directors of quality improvement and regulatory compliance and its Manager of Professional Practices:

**PURDUE**

**Stephen L. Seid**  
**Sr. Director, National Accounts**  
**and Trade Relations**  
**(203) 588-7315**

**TO:** Jim Lung

**FROM:** Steve Seid

**RE:** CVS Pharmacy

**DATE:** May 11, 2001

Jim, on May 2, 2001 Don Tasser and I met with three of the key pharmacy people at CVS. They were

- Barry Jasilli, R.Ph., J.D., Director, Quality Improvement
- Susan DeMonico, R.Ph., J.D., Director, Regulatory Compliance
- Sharon Galzarano, R.Ph., Manager of Professional Practices

The goal of the meeting was to talk about mutually beneficial initiatives with CVS to improve education with their pharmacists. We also wanted to reiterate our position on ensuring availability of OxyContin for appropriate patients. I think overall the entire meeting was very productive and the CVS people were extremely supportive.

Key issues discussed were as follows:

1. They were resolute in their commitment to good pharmacy practice. Part of that good pharmacy practice is ensuring availability of OxyContin for appropriate patients. Their goal is good patient care.
2. As a group they were vocal, particularly Barry Jasilli, indicating that they felt that Purdue was in many ways being victimized by the situation. That the product is not the issue, but that the abuser is the issue. He indicated that, from his perspective, we should be fighting back even harder. We should be pointing out the benefits of our brand.
3. CVS will be sending out a copy of our Abuse and Diversion Brochure to 4,100 pharmacies. Our letter will be personalized for the CVS pharmacist and co-signed by Barry Jasilli and Susan DeMonico. They will also be sending out a version of the Abuse and Diversion Brochure with their logo.
4. CVS will also put a copy of the Abuse and Diversion Brochure on their intranet site called RxNet.
5. They will be looking to utilize both of our written CE Programs, in particular, for new grads coming to work for CVS.
6. They talked about being more preemptive with our joint educational efforts. We will be setting up at least five programs at this time through CVS.
7. They talked about the possibility of co-hosting programs in areas of healthcare professionals. I don't know if there was a unanimous agreement among the CVS people, but we will follow up to see if that is possible. Susan DeMonico will be the point person for CE Programs.

I believe we are garnering some significant support with CVS. Don Tasser will ensure follow up on these key programs.

764. CVS's ties to PAP and Purdue were so deep that CVS even used PAP's and Purdue's logos on a cover letter when providing the aforementioned guide to CVS pharmacists:





**CVS/pharmacy**

June 2001

Dear CVS Pharmacists:

CVS is proud to participate in Partners Against Pain, a therapeutic alliance of pharmacists, physicians, nurses, and pain experts, sponsored by Purdue Pharma. We acknowledge the legitimate concern of pharmacists over the diversion of opioid medications.

That's why we recently developed, and have enclosed, "How to Stop Drug Diversion & Protect Your Pharmacy." Included in this guide are such helpful tips from the U.S. Drug Enforcement Administration, such as:

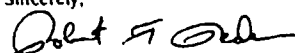
- How to detect prescriptions that have been "ripped" blank and rewritten
- Confirming prescriptions using a published phone number - not the number on the prescription - if you have doubts about any aspect of it

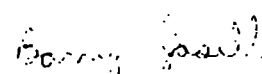
Treating people in pain is a top priority. Purdue is a leader in educating the healthcare community on effective pain management and the appropriate use of pain medicines. Why? Because we believe that education and open communication are keys to effective pain control.

Along with hundreds of educational programs and brochures, Partners Against Pain sponsors the award-winning website - [www.partnersagainstpain.com](http://www.partnersagainstpain.com) - which provides pain information, assessment tools, and support - 24 hours a day. We hope you and your customers will visit this site, and that the enclosed brochure will help you in your efforts to serve your customers and protect your pharmacy from drug diversion.

Provide the right patients, with the right pain medicine, at the right dosage, under the right supervision. Together, let's treat the pain. Please share a copy of this letter with your technician.

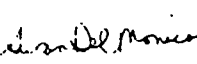
Sincerely,

  
Dr. Robert F. Reder, V.P.  
Medical Affairs & Worldwide Drug Safety  
Purdue Pharma L.P.

  
Barry Jasili, R.Ph., JD  
Director, Quality Improvement  
CVS Corporation

cc: Philip Keough, R.Ph.  
Director, Pharmacy Operations

Sharon Galzarano, R.Ph.  
Manager, Professional Practices

  
Susan DeMonico, R.Ph., JD  
Director, Regulatory Compliance  
CVS Corporation



One Stamford Forum, Stamford, Connecticut 06401-3411 Telephone (203) 588-5400 Fax (203) 588-5656  
[www.partnersagainstpain.com](http://www.partnersagainstpain.com)

## **B. CVS's Work with Endo**

765. CVS worked with Endo to increase patient adherence to continued use of opioids.

CVS had a crucial role in carrying out one of the key sales tactics in Endo's 2012 business plan.

766. Through a company called Catalina Health (“Catalina”), Endo was able to target OxyContin patients in areas where Opana ER had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients’ homes to encourage them to stay on Opana – even though prolonged use of opioids increases the risk of addiction and even though patients in pain presumably need no reminder to continue to take their pain medications.

767. The agreement between CVS and Endo was formalized in an agreement to promote, market, and advertise Endo’s opioid products via its “CVS Carecheck Plus Patient Education Service.” CVS contractually agreed to promote Opana ER to its customers (i.e., patients) at the point of sale, and it even insisted upon reviewing and approving the specific messaging used.

**C. CVS’s Work with Actavis**

768. CVS helped Actavis promote its opioids by working with Cardinal’s Marketing and Business Development team on programs designed to offer rebates and off-invoice discounts on products, with the aim being to “move [] product.”

**VII. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS.**

769. The Marketing Defendants created a vastly and dangerously larger market for opioids. The Supply Chain Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. This failure to maintain effective controls, to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, and to refuse to fill illegitimate prescriptions breached both their statutory and common law duties.

770. The Marketing Defendants’ scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. The Marketing Defendants’ deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC, opioid

prescriptions, as measured by number of prescriptions and morphine milligram equivalents (“MMEs”) per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) are used for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids.

771. In a 2016 report, the CDC explained, “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”<sup>249</sup> Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”<sup>250</sup>

**A. All Defendants Have, and Have Breached, Duties to Guard Against, Prevent, and Report Suspicious Orders and Unlawful Diversion.**

772. Multiple sources, including the common law duty to exercise reasonable care, impose duties on Defendants with respect to the supply of opioids.

773. Defendants are all required to register as either manufacturers, distributors, or dispensers pursuant to section 3310 of the New York Public Health Law and section 6808 of the New York Education Law. New York statutes and regulations impose non-delegable duties upon registrants to maintain effective controls against diversion, to maintain adequate records, and to design and operate a system to disclose to the registrant suspicious orders of controlled substances. N.Y. Pub. Health Law §§ 3313, 3316, 3331, 3350; N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.22, 80.65, 80.76, 910.2.

774. New York common law imposes (1) duties of reasonable care upon persons who market, distribute, and dispense opioids to maintain effective controls against diversion and to avoid

---

<sup>249</sup> Rose A. Rudd, et al., *2000-2014 Increases in Drug and Opioid Overdose Deaths*, 64 Mortality & Morbidity Weekly 1378 (2016).

<sup>250</sup> *Id.*

engaging in deceptive or misleading marketing practices; and (2) liability under the common law of nuisance against persons who negligently, recklessly, and/or intentionally cause the distribution or dispensing of narcotics through unauthorized channels and/or to persons to whom they should not be distributed or dispensed.

775. Each Defendant was registered with the New York State Board of Pharmacy to possess and offer for sale “drugs, prescriptions or poisons.” N.Y. Educ. Law § 6808.

776. The Marketing and Distributor Defendants may not engage in “unprofessional conduct.” N.Y. Comp. Codes R. & Regs. tit. 8, §§ 29.1(a) (resident defendants), 63.8(b)(2) (nonresident defendants). Such conduct includes:

- (1) willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession;
- (2) exercising undue influence on the patient or client, including the promotion of the sale of services, goods, appliances or drugs in such manner as to exploit the patient or client for the financial gain of the practitioner or of a third party;
- ....
- (5) conduct in the practice of a profession which evidences moral unfitness to practice the profession;
- (6) willfully making or filing a false report, or failing to file a report required by law or by the Education Department, or willfully impeding or obstructing such filing, or inducing another person to do so;
- ....
- (12) advertising or soliciting for patronage that is not in the public interest:
  - (i) Advertising or soliciting not in the public interest shall include, but not be limited to, advertising or soliciting that:
    - (a) is false, fraudulent, deceptive or misleading;

N.Y. Comp. Codes R. & Regs. tit. 8, §§ 29.1(b).

777. Under section 6808 of the New York Education Law, “[e]very owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy.” It is improper for a pharmacy to knowingly dispense prescription drugs when the prescription “is not issued for legitimate medical purposes.” N.Y. Comp. Codes R. & Regs. tit. 10, § 910.2. Moreover, New York law forbids dispensing controlled substances “to an addict or habitual user.” N.Y. Pub. Health Law §§ 3331(1), 3350; N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.65, 80.76.

Therefore, the National Retail Pharmacies are responsible and can be held accountable for improperly dispensing prescription opioids.

778. Defendants also had legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescription opioids under New York law: “The licensee shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders.” N.Y. Comp. Codes R. & Regs. tit. 10, § 80.22.

779. “Suspicious orders” include but are not limited to orders of an unusual size, orders of unusual frequency, or orders deviating substantially from a normal pattern. *Id.* These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order must be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

780. Defendants have a duty to report suspicious orders or prescriptions in order to prevent diversion even if diversion is only possible rather than affirmatively proven. *See* N.Y. Comp. Codes R. & Regs. tit. 10, § 80.110 (requiring any person authorized to possess controlled substances to “promptly notify the department of each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person” (emphasis added)).

781. In addition to reporting all suspicious orders, the Marketing and Distributor Defendants must also stop shipment on any order which is flagged as suspicious and may only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient

determines that the order is not likely to be diverted into illegal channels.<sup>251</sup> Regardless, all flagged orders must be reported.

782. Prescription opioids are regulated for the purpose of providing a “closed” system to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market.<sup>252</sup>

783. “Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.”<sup>253</sup>

784. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and the consequent dependency, abuse, addiction, morbidity, and mortality, along with the costs imposed upon Plaintiffs and others associated with responding to patients affected by these conditions.

785. Wholesalers such as the Distributor Defendants have close financial relationships with both the Marketing Defendants and the customers that dispense opioids, for whom the Distributor Defendants provide a broad range of value-added services that render the Distributor Defendants uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated

<sup>251</sup> See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. 2017).

<sup>252</sup> See 1970 U.S.C.C.A.N. 4566, 4571–72.

<sup>253</sup> Brief for Healthcare Distribution Mgmt. Association and National Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at \*22 (hereinafter “Brief for HDMA and NACDS”). The Healthcare Distribution Mgmt. Ass’n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. See generally HDA, *About*, <https://www.healthcaredistribution.org/about> (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, *Mission*, <https://www.nacds.org/%20about.mission> (last accessed Aug. 1, 2018).

ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."<sup>254</sup> Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

786. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the Healthcare Distribution Alliance, an industry group of pharmaceutical manufacturers and distributors, includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to "downstream registrants," meaning pharmacies or other dispensaries. The Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders and problematic prescribing and dispensing practices.

787. A dramatic example of the use of prescription information provided by IMS Health, a data company, was described in Congressional testimony between Representative James C. Greenwood and Michael Friedman, Purdue's COO and executive vice president:

Mr. Greenwood: Well, why do you want that [IMS Health] information then?

Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. Greenwood. And so the use of it—and I assume that part of it—a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians—you look to see if your marketing practices are increased in sales. And, if not, you go back

<sup>254</sup> *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

to the drawing board with your marketers and say, how come we spent “X” number of dollars, according to these physicians, and sales haven’t responded. You do that kind of thing. Right?

Mr. Friedman: Sure.<sup>255</sup>

**B. Defendants Used Trade and Other Organizations.**

788. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum and the Healthcare Distribution Alliance.

**1. Pain Care Forum**

789. The Pain Care Forum (“PCF”) is a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. Lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

790. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”<sup>256</sup> Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.<sup>257</sup>

791. Defendants who stood to profit from expanded prescription opioid use are members of or participants in the PCF.<sup>258</sup> In 2012, membership and participating organizations included Marketing Defendants Endo, Purdue, Actavis, and Cephalon. But the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the Healthcare Distribution Alliance.<sup>259</sup>

---

<sup>255</sup> *Oxycontin: Its Use and Abuse*, *supra*.

<sup>256</sup> Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (Sept. 19, 2017), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>. (emphasis added).

<sup>257</sup> *Id.*

<sup>258</sup> PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

<sup>259</sup> *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation.



792. The PCF thus allowed the Marketing and Supply Chain Defendants to engage in coordinated conduct to ensure an oversupply of opioids.

## 2. Healthcare Distribution Alliance

793. The Healthcare Distribution Alliance (“HDA”) was, until 2016, known as the Healthcare Distribution Management Association (“HDMA”).

794. The HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants as well as Marketing Defendants such as Actavis, Endo, Purdue, Mallinckrodt, and Cephalon were members of the HDA.<sup>260</sup> Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Marketing Defendants by advocating the many benefits for members, including “strengthening . . . alliances.”<sup>261</sup>

795. Beyond strengthening alliances, the benefits of HDA membership included: the ability to “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference;” “networking with HDA wholesale distributor members;” “opportunities to host and sponsor HDA Board of Directors events;” and opportunities to “participate on HDA committees, task forces and working groups with peers and trading partners” and “make connections.”<sup>262</sup> The HDA and the Supply Chain Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Marketing and Supply Chain Defendants.

796. The application for manufacturer membership in the HDA further indicates the level of connection among Defendants and the level of insight that they had into each other’s businesses.<sup>263</sup>

*Executive Committee, Healthcare Distribution Alliance* (last accessed on Aug. 1, 2018), <https://www.healthcaredistribution.org/about/executive-committee%20>.

<sup>260</sup> *Manufacturer Membership, Healthcare Distribution Alliance*, <https://www.healthcaredistribution.org/about/membership/manufacturer> (last accessed Aug. 1, 2018).

<sup>261</sup> *Id.*

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the applicant identify a key contact and any additional contacts from within its company.

797. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Cardinal, Henry Schein, and their subsidiaries.

798. The closed meetings of the HDA’s councils, committees, task forces, and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

799. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”<sup>264</sup> The conferences also gave the Marketing and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”<sup>265</sup> The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.<sup>266</sup>

800. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces, and working groups, including:

<sup>264</sup> *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference-blc-for-manufacturers> (last accessed Aug. 1, 2018, and no longer available).

<sup>265</sup> *Id.*

<sup>266</sup> *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, [distribution-management-conference](#) (last accessed Aug. 1, 2018).

- a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."
- b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.
- e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

801. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.<sup>267</sup> For example, on April 27, 2011, the HDA offered a webinar to "accurately and effectively exchange business transactions between distributors and manufacturers . . . ." On information and belief, the

---

<sup>267</sup> *Webinars, Healthcare Distribution Alliance*, <https://www.healthcaredistribution.org/resources/webinar-leveraging-edl> (last accessed Sept. 14, 2017).

Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

802. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together. Defendants operated as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

803. The HDA and PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals, and they demonstrate that Defendants' leaders communicated and cooperated.

804. Publications and guidelines issued by the HDA confirm that Defendants utilized their HDA membership to form agreements. Specifically, in the fall of 2008, the HDA published *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of [HDA] members contribut[ing] to the development of this publication" beginning in late 2007.

805. This statement and the Industry Compliance Guidelines themselves support the allegation that Defendants utilized the HDA to form agreements about their approach to their legal duties with respect to the distribution of controlled substances. As John M. Gray, President/CEO of the HDA, stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance: an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders or to prevent diversion.

806. Defendants worked together to control the flow of information and to influence governments to pass legislation that supported the use of opioids and limited the authority of law

enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

807. Defendants also had obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

808. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be revealed. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency.

809. The desired consistency was achieved. As described below, no Defendant adequately reported suspicious orders, and the flow of opioids continued unimpeded.

**C. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.**

810. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these opioids out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Distributors have a critical obligation to maintain effective controls against diversion because they handle such large volumes of controlled substances and because distributors' knowledge of their customers and their orders makes them the first line of defense against the flow of legal pharmaceutical controlled substances into the illicit market. Should a distributor breach this obligation, the closed system of distribution, designed to prevent diversion, collapses.<sup>268</sup>

811. Defendants were well aware they had an important role to play in this system and also knew or should have known that their failure to comply with their obligations would have serious consequences.

---

<sup>268</sup> See Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. No. 14-2 (D.D.C. Feb. 10, 2012).

**D. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers.**

812. The data that reveals and/or confirms the identity of each wrongful opioid distribution is hidden from public view in the DEA's confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of Defendants but has not been disclosed to the public.

813. Publicly available information confirms that Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids.

814. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy, and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe the red flags of diversion;
- d. the Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. the Marketing Defendants purchased chargeback data (in return for discounts to the Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

815. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities

that they knew or should have known exceeded any legitimate market for opioids—even if the wider market for chronic pain had been entirely legitimate (which it was not).

816. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids.<sup>269</sup> The “know your customer” questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and others. These questionnaires put the recipients on notice of suspicious orders.

817. At all relevant times, Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They purchased this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, Arclight, Scriptorline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”). The Data Vendors’ information purchased by Defendants allowed them to view, analyze, compute, and track their competitors’ sales, and to compare and analyze market share information.<sup>270</sup> It also allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc.

---

<sup>269</sup> U.S. Dep’t of Justice Drug Enforcement Administration, *Suggested Questions a Distributor should ask prior to shipping controlled substances*, [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_industry/14th\\_pharm\\_level/ques.pdf](https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm_level/ques.pdf); Richard Widup, Jr. & Kathleen H. Dooley, *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLP, [https://www.mcguirewoods.com/news-resources/publications/lifesciences/product\\_diversion\\_beyond\\_pdma.pdf](https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

<sup>270</sup> A Verispan representative testified that the Supply Chain Defendants use the prescribing information to “drive market share.” *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, at \*9-10 (Feb. 22, 2011).

818. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.<sup>271</sup>

819. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies created by McKesson (Source) and Cardinal (ArcLight), provided Defendants with charts analyzing the weekly prescribing patterns of multiple physicians organized by territory regarding competing drugs and then analyzed the market share of those drugs.<sup>272</sup>

820. This information allowed Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.<sup>273</sup> Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

821. Defendants refused to identify, investigate, and report suspicious orders when they became aware of the same despite their actual knowledge of drug diversion. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012<sup>274</sup> and 117 recommended decisions in registrant actions from the Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.<sup>275</sup>

---

<sup>271</sup> Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills* fig.2 at 3 <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf> (last accessed Aug. 1, 2018).

<sup>272</sup> *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, at \*467-71 (Feb. 22, 2011).

<sup>273</sup> In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; see also Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at \*204 (Feb. 22, 2011).

<sup>274</sup> U.S. Dep't of Justice, Evaluation and Inspections Div., Office of the Inspector Gen., *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf> (hereinafter "The Drug Enforcement Administration's Adjudication of Registrant Actions").

<sup>275</sup> *Id.*



822. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression). Stupid decision for a teen to make...yes... but do they really deserve to die?

823. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics raised (or should have raised) numerous red flags.

824. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.<sup>276</sup> In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."<sup>277</sup>

825. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members" and that she felt "very certain that this an organized drug ring."<sup>278</sup> She wrote, "This is clearly diversion.

---

<sup>276</sup> *Pain Killer*, *supra*, at 298–300.

<sup>277</sup> *Id.*

<sup>278</sup> Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016),

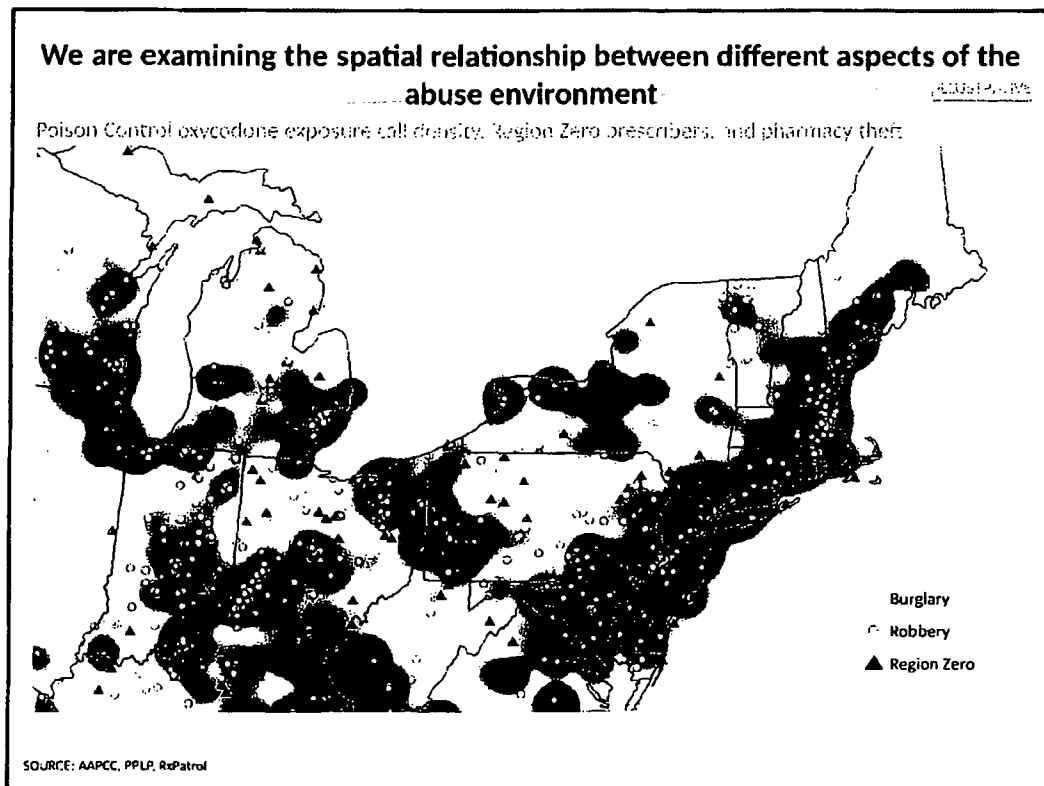
Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."<sup>279</sup> This pill mill was not only distributing opioids locally; over a million pills were transported to the City of Everett, Washington, a city of around 100,000 people. Couriers drove up I-5 through California and Oregon or flew from Los Angeles to Seattle. The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

826. At Purdue, the Sacklers and the Purdue Officers were aware that Purdue regularly received "Reports of Concern" about abuse and diversion of opioids, reports of other adverse events, and calls to Purdue's compliance "hotline." In July 2007, staff told the Sacklers and the Purdue Officers that more than 5,000 adverse events had been reported to Purdue in just the first three months of the year. Staff also told the Sacklers and the Purdue Officers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during the second quarter of 2007. Staff reported to the Sacklers that they completed only 21 field inquiries in response. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

827. Purdue also tracked prescribers from whom there was a substantial possibility of opioids being diverted or, at a minimum, grossly over-prescribed. It described these prescribers collectively as "Region Zero" and even generated a map, presented to the Sacklers, the Purdue Officers, and the entire Purdue Board, correlating these prescribers with poison control calls and pharmacy thefts. The map shows that several pharmacy robberies and burglaries occurred New York.

---

<sup>279</sup> <http://www.latimes.com/projects/la-me-oxycontin-part2>.  
<sup>280</sup> *Id.*



*Map presented to the Purdue Board in 2011*

828. Despite its awareness of the spatial association between these high prescribers, overdose, and criminality, Purdue made a conscious decision not to report these prescribers to authorities.

829. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers. However, this was done not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement.

830. The Marketing Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the

prescriptions of the biggest prescribers, particularly through aggressive, high-frequency detailing visits.

831. This focus on marketing to the highest prescribers demonstrates that the Marketing Defendants were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

832. But given the closeness with which they monitored prescribing patterns, Defendants either knew or chose not to know of the obvious drug diversions. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

833. As discussed above, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

**E. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion.**

834. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

835. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations. These agencies and regulators have also uncovered especially blatant wrongdoing. A few examples will suffice:

836. In 2017, the DOJ fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The

government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

837. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated federal regulations and statutes in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b)”;
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”;
- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

838. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, on numerous causes of action, including violations of consumer credit and protection laws, antitrust laws, and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal, shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that Defendants failed to control the supply chain or to report and take steps to halt

suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

839. Henry Schein, too, is a repeat offender. Since the company's inception, it has been subjected to repeated disciplinary actions across the United States for its sale and/or distribution of dangerous drugs to persons or facilities not licensed or otherwise authorized to possess such drugs.

840. In 2014, Henry Schein Animal Health was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity not holding a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy in 2015.

841. Records from a disciplinary proceeding against a Wisconsin-licensed medical practitioner also reveal that from May 2005 through September 2006, Henry Schein continued to deliver opioids to the provider, even though his license had been suspended for inappropriate prescribing of opioids.

842. Defendants have admitted to disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control supply, prevent diversion, and report and take steps to halt suspicious orders.

**F. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement.**

843. When a manufacturer or distributor does not report or stop suspicious orders, controlled substances may be dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

844. After being caught failing to comply with particular obligations at particular facilities, the Supply Chain Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

845. The Supply Chain Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous

drugs. For example, Cardinal claims, “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria.” A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

846. Similarly, AmerisourceBergen has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokesperson also provided assurance that “[a]t AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

847. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Supply Chain Defendants, through their trade associations HDMA and the National Association of Chain Drug Stores (“NACDS”), filed an amicus brief that made the following statements:<sup>281</sup>

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

---

<sup>281</sup> Brief for HDMA and NACDS, *supra*, at \*3–4, \*25.

848. Through these and similar statements, the Supply Chain Defendants not only acknowledged that they understood their obligations under the law, but they further asserted that their conduct was in compliance with those obligations.

849. Misrepresentations of compliance with their legal duties and their cooperation with law enforcement were not limited to the Supply Chain Defendants. For instance, Mallinckrodt claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts, “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts [and] monitoring for suspicious orders of controlled substances . . . .”

850. Likewise, Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse” and its “strong record of coordination with law enforcement.”<sup>281</sup>

851. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid epidemic.

852. Purdue’s website asserts: “We are acutely aware of the public health risks these powerful medications create . . . . That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . .”<sup>282</sup> Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law

---

<sup>281</sup> Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs> (hereinafter “*Setting The Record Straight*”).

<sup>282</sup> Purdue, *Opioids With Abuse-Deterrent Properties*, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties> (last accessed Aug. 1, 2018).



enforcement, and government.”<sup>283</sup> And, responding to criticism of Purdue’s failure to report suspicious prescribing to regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”<sup>284</sup>

853. These public pronouncements create the false impression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

854. Public statements by Defendants and their associates gave regulators, prescribers, and the public the false and misleading impression that Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs and that Defendants worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

855. Defendants’ misrepresentations ultimately delayed an adequate response to the opioid crisis.

**G. The Marketing Defendants’ Failed to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders.**

856. The same legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescription opioids imposed on the Distributor Defendants were also required of the Marketing Defendants under New York law. Like the Distributor Defendants, the Marketing Defendants were required to obtain a license to manufacture and distribute controlled substances, like prescription opioids. N.Y. Pub. Health Law § 3310; N.Y. Comp. Codes R. & Regs. tit. 10, § 80.10. One requirement for initial licensure and for renewal is “maintain[ing] effective control against

---

<sup>283</sup> *Id.*

<sup>284</sup> *Setting The Record Straight, supra*. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

diversion of controlled substances.” N.Y. Pub. Health Law §§ 3312(1)(c), 3313(1)(a), 3316(1)(a). Similarly, the Marketing Defendants must comply with all applicable state and federal laws and regulations regarding controlled substances. *Id.* §§ 3312(1)(d), 3313(1)(b), 3316(1)(b). The Marketing Defendants failed to maintain effective controls as required and to comply with the other requirements imposed by New York statutes and regulations.

857. Like the Distributor Defendants, the Marketing Defendants breached these duties.

858. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer, and, in exchange for the payment, the distributor identifies to the manufacturer the product, the volume, and the purchasing pharmacy. Thus, the Marketing Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the Distributor Defendants.

859. The statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to design and operate a system to disclose suspicious orders of controlled substances and to maintain effective controls against diversion.

860. Through, *inter alia*, the chargeback data, the Marketing Defendants could have monitored suspicious orders of opioids.

861. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by law.

862. The Marketing Defendants’ failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

863. The Marketing Defendants have misrepresented their compliance with the laws --regulating controlled substances.

864. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and that were a substantial contributing factor to and proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

865. The Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States. The following subsections describe the conduct of specific Marketing Defendants by way of example.

#### 1. Mallinckrodt

866. The DOJ has recently confirmed the suspicious order obligations clearly imposed by law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.<sup>285</sup>

867. In the press release accompanying the settlement, the Department of Justice stated:

[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring ("SOM") requirements exist to prevent excessive sales of controlled substances, like oxycodone. . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .<sup>286</sup>

868. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers, "As a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."<sup>287</sup> Mallinckrodt further acknowledged that it "recognizes the importance

<sup>285</sup> See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

<sup>286</sup> *Id.*

<sup>287</sup> Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug

of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 C.F.R. § 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

869. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

- a. Mallinckrodt’s alleged failure to distribute oxycodone and hydrocodone products in a manner authorized by its registration and Mallinckrodt’s alleged failure to operate an effective SOM system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt’s alleged failure to conduct adequate due diligence of its customers;
- b. Detect and report to the DEA orders of unusual size and frequency;
- c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
  - i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
  - ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
  - iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. Use “chargeback” information from its distributors to evaluate suspicious orders; and

Enft Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmu/press-release/file/986026/download> (hereinafter “2017 Mallinckrodt MOA”).

- e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.<sup>288</sup>

870. Mallinckrodt acknowledged that “[a]s part of [its] business model Mallinckrodt collects transaction information, referred to as chargeback data, from [its] direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”<sup>289</sup>

## 2. Teva

871. In 2012, possibly in response to the DEA’s heightened vigilance and inspection of opioid distributor Suspicious Order Monitoring (“SOM”) systems, Teva hired consultants to perform a review of Teva’s SOM system. The resulting report in September 2012 called Teva’s existing SOM system “rudimentary” and noted that Teva had no written SOM procedures in place and had never reported a single suspicious order up to that point. Ultimately, Teva decided not to hire any outside consultant to design and operate the SOM system, but rather decided to do it in house.

872. In early 2013, Teva hired an AmerisourceBergen employee to run its SOM program and design a new system. That new employee was fired within 90 days after he contacted a downstream customer about a potentially suspicious order.

873. In January 2014, Teva hired Joe Tomkiewicz (“Tomkiewicz”), who had also worked for AmerisourceBergen, to design Teva’s program. Tomkiewicz joined Teva after being visited at his home by DEA agents on two occasions, where they advised him to get a lawyer presumably with regard to an investigation into AmerisourceBergen’s SOM program and opioid diversion.

874. Tomkiewicz ultimately designed an SOM program for Teva which he coined “DefOps,” which means “Defensible Operations.” Tomkiewicz named it that because it was intended to be a system Teva could use to keep itself out of trouble with the DEA and because it “sounded

---

<sup>288</sup> *Id.* at 2–3.

<sup>289</sup> *Id.* at 5.

good.” The written SOPs for the system were approved in August 2014, nearly two years after Teva’s consultant told Teva that it needed to have written procedures in place.

875. The SOPs for the DefOps program kept the key investigatory role for suspicious order monitoring in the hands of Teva’s sales department. This organizational structure created a conflict because the sales department would have also directed customer service to contact the customer for initial investigation and to send a sales rep to the customer if the response was not satisfactory.

876. Teva’s parent company audited Teva’s DEA compliance department in 2015 without interviewing anyone from customer service or the sales department, despite their critical role in interfacing directly with customers during any investigation of suspicious orders. This report was critical of the compliance department and the SOM program. The report stated that Teva investigated 10,000-line orders per month of Schedule II products; of these 10,000 orders, 95% were automatically released. Only 5% of the orders were placed on hold to be manually checked. The report found the DEA compliance department was in “noncompliance with DEA requirements” and was at “High Risk” of DEA regulatory action and that the SOM program was at “Moderate Risk” for such action.

877. For the SOM program, the report focused primarily on the fact that suspicious orders were cleared through the decisions of a single person (Tomkiewicz), which exposed the system to the risk of mistaken releases. The audit noted that the SOM program must clear 5,000 pending, potentially suspicious, line orders per month while under pressure from the sales department to quickly clear the order and not to disrupt their customers’ opioid supply chain.

878. Teva’s SOM may still be inadequate. Plaintiffs have found no attempt by Teva to obtain verification or an audit from any trained outside consultant of the design and operation of their SOM system. Additionally, Teva’s SOM has reported and stopped very few suspicious orders.

879. Teva reported its first ever suspicious order to the DEA on February 13, 2013. It was an order from a small distributor called Capital Wholesale Drug. The suspicious order report states that the order quantity is not within the customer’s normal purchasing pattern, yet fails to elaborate on the customer’s historic purchasing quantity. The report provides virtually no information about

the suspicious order, nor does it offer to provide any information from Teva's investigation, such as its findings or the reasons the order was suspicious. This uninformative report is typical of all reports Teva submitted to the DEA.

880. From 2013 through 2016, Teva reported only 6 suspicious orders out of 600,000 total line orders, or 0.00001% of all line orders it was processing.

881. Tomkiewicz claimed at least 18 suspicious orders were reported in 2017, but only five such reports are supported by documentary evidence. For 2018, Tomkiewicz testified he reported "close to 50" suspicious orders, but only 15 reports are documented.

### 3. Janssen

882. Janssen's SOM algorithm was also materially deficient in that it was narrowly designed such that an order would only be compared to previous orders of the same product at the same strength.

883. Janssen had access to transactional sales data, including charge-back data, wholesalers' inventory and sales data, and third-party data. Janssen should have, but did not, use this data in its SOM program.

884. While their sales and marketing teams extensively utilized this type of data for sales and to target high-volume prescribers, the Marketing Defendants failed to incorporate any of this sales data to monitor suspicious prescribers.

### H. The Distributor Defendants Unlawfully Distributed Opioids.

885. The Distributor Defendants owe a duty under, *inter alia*, New York common law and statutory law, to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted. New York law and regulation require distributors of Schedule II drugs, including opioids, to maintain effective control against the diversion of controlled substances. N.Y. Pub. Health Law §§ 3312(1)(c), 3313(1)(a), 3316(1)(a); N.Y. Comp. Codes R. & Regs. tit. 10, § 80.22.

886. In addition to reporting all suspicious orders, distributors must also stop shipment on

any order which is flagged as suspicious. The only flagged orders that may be shipped are those that the distributor can determine, after conducting due diligence, are unlikely to result in diversion of scheduled drugs into illegal channels.<sup>290</sup>

887. Whether or not a flag can be resolved, the order is still suspicious and must be reported.<sup>291</sup>

888. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

889. Each Distributor Defendant repeatedly and purposefully breached its duties under the law. Such breaches are a direct and proximate cause of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

890. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their profits through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

891. The unlawful diversion of prescription opioids is a direct and proximate cause of prescription opioid abuse, addiction, morbidity, and mortality. The social and financial costs of these conditions are borne by, among others, individuals, families, and hospitals such as Plaintiffs.

#### **I. The Distributor Defendants Breached Their Duties.**

892. Each Distributor Defendant was required to be licensed by the Commissioner of Health of the State of New York. Each Distributor Defendant was licensed as a wholesale distributor

---

<sup>290</sup> See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 15-11355 (D.C. Cir. June 30, 2017).

<sup>291</sup> *Id.*



of Schedule II controlled substances with a duty to comply with all security requirements imposed under the New York State Controlled Substances Act.

893. A distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger a wholesaler's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the distributor's customer base and the patterns throughout the relevant segment of the industry.

894. As the DEA advised the Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."<sup>292</sup>

895. The DEA's September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."<sup>293</sup> The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."<sup>294</sup> The DEA warns that "even just one distributor that uses its

---

<sup>292</sup> See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012) (hereinafter "Rannazzisi Letter") ("This letter is being sent to every commercial entity in the United States registered with the Drug Enf't Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

<sup>293</sup> *Id.* at 2.

<sup>294</sup> *Id.* at 1.

DEA registration to facilitate diversion can cause enormous harm.”

896. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.<sup>295</sup> This letter reminds the Distributor Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”<sup>296</sup> The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 [U.S.C. §§] 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.<sup>297</sup>

897. The Distributor Defendants have admitted that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”<sup>298</sup>

898. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the HDA explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process and note in particular: “If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the

<sup>295</sup> *Id.* at 2.

<sup>296</sup> *Id.* at 1.

<sup>297</sup> *Id.* at 2.

<sup>298</sup> See Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass’n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep’t of Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at \*10 (hereinafter “Brief of HDMA in Support of Cardinal”).

distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.”<sup>299</sup>

899. The Federal Trade Commission has also recognized distributors’ unique role. Since their inception, the Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, the Distributor Defendants also offer their pharmacy or dispensing customers a broad range of added services. For example, the Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. The Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.<sup>300</sup> As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the additional services they offer, the Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

900. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew or should have known prescription opioids were likely to be diverted.

901. The Distributor Defendants’ violations of public safety statutes and regulations constitute *prima facie* evidence of negligence under New York law.

---

<sup>299</sup> Healthcare Distribution Mgmt. Ass’n (HDMA), Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, *Cardinal Health, Inc. v. Holder*, Doc. No. 1362415 (App’x B), No. 12-5061 (D.C. Cir. Mar. 7, 2012).

<sup>300</sup> See *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC’s motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.).

902. The unlawful conduct by the Distributor Defendants was purposeful and intentional. The Distributor Defendants refused to abide by the duties imposed by New York law which are required to legally acquire and maintain a license to distribute prescription opioids.

903. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they acted with a conscious disregard for the rights and safety of other persons, and those actions had a great probability of causing substantial harm.

#### **1. Inadequate Scrutiny of Customers**

904. None of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective new customers or their existing customers. New customers were routinely on-boarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted when existing customers made suspicious orders—even when compliance staff flagged those orders as suspicious, blocked them, and reported them to the authorities.

905. Indeed, the Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same year, month, or even week without conducting any additional due diligence. In fact, salespeople would sometimes warn customers when they were approaching their monthly threshold limits for ordering certain categories of controlled substances, effectively assisting their customers in evading compliance reviews that would have otherwise occurred by manipulating the timing and volume of their orders.

906. Even where customers had to be blocked from ordering opioids in excess of their monthly threshold multiple times within a month, the Distributor Defendants would often allow those customers to resume ordering opioids the next month, at the same volume as before, without conducting any follow up investigation.

907. None of the Distributor Defendants conducted periodic, unexpected due diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies could go for years

without the Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, the customers were often warned in advance, giving them an opportunity to escape scrutiny and Defendants an opportunity to bury their heads in the sand.

## 2. Failure to Detect, Block, and Report Suspicious Orders

908. The Distributor Defendants failed to report "suspicious orders," which the Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

909. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

910. The Distributor Defendants breached their duties to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opiates and/or orders from areas in which the Distributor Defendants knew or should have known opioids were likely to be diverted.

911. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

912. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.<sup>301</sup> While the Distributor Defendants' policies nominally allowed for compliance staff to identify any order as suspicious, as a matter of practice, only orders that exceeded a customer's monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed due to their unusual size or frequency or their departure from the customers' normal ordering patterns were never even checked to determine whether they were suspicious. Because the Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products and so enabled those customers to "game"

<sup>301</sup> See *Cardinal Health, Inc. v. Horder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).



these limits, suspicious orders were improperly excluded from compliance review, when they all should have been checked to see whether the customers were deliberately structuring their orders to evade scrutiny.

913. Even as to orders that exceeded customers' monthly thresholds, the Distributor Defendants routinely failed to accurately identify those orders as suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer or even for no documented reason at all. Moreover, even when the Distributor Defendants did identify orders as suspicious and did block them from delivery, they routinely failed to do so, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer, even when they were made within the same month, week, or even day.

914. The sheer volume of prescription opioids distributed to pharmacies in various areas or to pharmacies from which the Distributor Defendants knew or should have known that the opioids were likely to be diverted was excessive for the medical need of the relevant community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.<sup>302</sup>

### **3. Failure to Adequately Maintain Accessible Data Concerning Customers and Prescribers**

915. None of the Distributor Defendants systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers, in order to allow for meaningful future compliance efforts.

916. The Distributor Defendants did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to **forbid** such inquiries, willfully blinding themselves to one of the most important indicators of diversion.

---

<sup>302</sup> *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS LLC, d/b/a CVS Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

917. While compliance staff and/or third-party investigators retained by the Distributor Defendants would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified unless they had personally handled the earlier investigation and happened to remember the prescriber's name. Similarly, they made no effort to collect and compare information about pharmacies that had made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

#### **4. Failure to Report Violations to Government Authorities**

918. The Distributor Defendants failed to promptly report compliance violations. If any of the Distributor Defendants had conducted periodic audits of their own records, customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have been obliged to report hundreds, if not thousands, of violations at a time.

919. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

**J. Each of the Distributor Defendants Engaged in Wrongful Conduct.**

**1. Cardinal**

**a. Cardinal's Flawed Written Policies Enabled Opioid Diversion.**

920. Cardinal's written policies for compliance were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in 2008 and have since undergone several revisions.

921. These policies were fundamentally flawed in that they were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, the SOPs were not readily available even to the employees charged with implementing them.

922. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

- a. Allowed compliance staff to approve onboarding new accounts with no formal mechanism to ensure review and approval by a supervisor;
- b. Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information; and
- c. Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time.

**b. Cardinal Failed to Effectively Prevent Diversion in Practice.**

923. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train compliance staff and sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

924. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of



the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by individuals with no prior experience in supervising investigative functions.

925. Moreover, Cardinal failed to provide meaningful training to these unqualified compliance personnel and to sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

926. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags.

927. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices prioritized sales over regulatory obligations.

928. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

- a. Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;
- b. Expanded the geographic territories of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;
- c. Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and

- d. Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

929. As to existing customers, Cardinal routinely failed to follow the SOPs. Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs.

930. Even where Cardinal did block customers' orders and report them, it routinely took no steps to suspend or terminate those customers pending further investigation and instead allowed them to continue receiving their threshold amount of opioids month after month, regardless of whether they continued to make additional suspicious orders.

931. For example, between 2012 and 2017, Cardinal reported twelve or more opioid-related suspicious orders for at least one year—the equivalent of one per month—for hundreds of pharmacies. Those pharmacies with known red flags in their shipment orders and prescription data. More than half of these pharmacies exceeded the 90th percentile in the State in terms of (a) opioid volume shipped; (b) oxycodone volume shipped; and (c) median strength of opioids prescribed per day. Nonetheless, even after reporting twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for more than three years. Among this group of suspect pharmacies that Cardinal did nothing to control were particularly egregious cases in which Cardinal found more than 50 opioid-related suspicious orders per year—the equivalent of one suspicious order per week for three or more consecutive years.

932. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacies' opioid prescriptions. By itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges.

933. Examples of egregious cases identified in an investigation by New York's Attorney

General included:

- a. A pharmacy in the 99th percentile in the state, to which Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, this pharmacy continued to receive opioids from Cardinal.
- b. A pharmacy in the 95th percentile in the state, to which Cardinal, from 2012 to 2018, shipped more than 20,000 grams of opioids, the equivalent of about thirteen 30mg oxycodone pills for every person in the county.
- c. A pharmacy in the 90th percentile where more than 20% of its customers have received opioid prescriptions by three or more doctors in a six-year period, and to which Cardinal continued to ship opioids after other distributors had issued 223 suspicious order reports.
- d. A pharmacy in the 99th percentile where approximately 60% of prescriptions were written by prescribers who were later indicted or convicted, and to which Cardinal has failed to issue a single suspicious order report as of December 2017.

934. Even if Cardinal had conducted due diligence to investigate its high-volume opioid customers, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

935. Due to these flaws in its SOM, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations as likely sources of diversion.

**c. Cardinal Was Put on Notice of its Wrongful Conduct.**

936. In addition to numerous instances in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice by government agencies that it was not fulfilling its duties.

937. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States (the "2008 Cardinal Settlement

Agreement”).<sup>303</sup> These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue internet pharmacy websites.<sup>304</sup>

938. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations.”<sup>305</sup> However, in 2012, the DEA issued an “immediate suspension order,” suspending Cardinal’s registration for its drug distribution facility in Lakeland, Florida. That order stated, “Despite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].”<sup>306</sup> For example, from “2008-2009, Cardinal’s sales to its top four retail pharmacies [in Florida] increased approximately 803%. From 2009 to 2010, Cardinal’s sales to its top four retail pharmacies [in Florida] increased 162%.”<sup>307</sup>

939. To settle this action, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.<sup>308</sup>

<sup>303</sup> Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), [https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal\\_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us](https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us); Press Release, U.S. Att’y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), [https://www.justice.gov/archive/usao/co/news\\_2008/October08/10\\_2\\_08.html](https://www.justice.gov/archive/usao/co/news_2008/October08/10_2_08.html).

<sup>304</sup> *Id.*

<sup>305</sup> *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).

<sup>306</sup> *Id.* at ¶ 3.

<sup>307</sup> *Id.* at ¶ 4.

<sup>308</sup> *Id.*

940. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for \$44 million.<sup>309</sup> The settlement resolved DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.<sup>310</sup> The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.<sup>311</sup> The settlement also covered a Cardinal subsidiary, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders for controlled substances at an unusually frequent rate.<sup>312</sup>

## 2. AmerisourceBergen

### a. AmerisourceBergen's Flawed Written Policies Enabled Opioid Diversion.

941. AmerisourceBergen is the nation's third largest drug distributor. AmerisourceBergen's written policies for compliance were and are contained within its Diversion Control Program and its Order Monitoring Program ("COMP"). The programs are administered by AmerisourceBergen's Corporate Security and Regulatory Affairs ("CSRA"). From 2007 to 2015, the program's specifics were scattered through a series of policy and procedure documents. These documents were not uniform for AmerisourceBergen and its subsidiary, Bellco Health, which it acquired in 2007.

942. AmerisourceBergen's compliance policies are flawed from the point of initial new customer onboarding. Since 2007, AmerisourceBergen has generally required a customer questionnaire, a site visit, license verification, and online investigation as part of its new customer due diligence process. A central component of AmerisourceBergen's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form"). The form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, and usage

<sup>309</sup> U.S. Att'y Office, Dist. of Md., *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

<sup>310</sup> *Id.*

<sup>311</sup> *Id.*

<sup>312</sup> *Id.*

numbers for specific high-risk drugs, among other questions. Though the form requests information about top prescribers of opioids, it is not AmerisourceBergen's policy to perform news searches on those prescribers as part of the new customer procedure, and controlled substances could account for a significant amount of prescriptions dispensed before triggering additional investigation.

943. AmerisourceBergen does not require new customers to provide usage reports or dispensing data as part of the onboarding process. By relying on customers to self-report without any documented verification, AmerisourceBergen does not fulfill its obligation of truly knowing its customers' business practices.

944. Both prior to and after program revision, AmerisourceBergen's policies have allowed for frequent threshold manipulation to avoid orders being held for review, unfilled, or reported as suspicious. Staff reviewing the form have high benchmarks for these numbers before considering them red flags.

945. AmerisourceBergen's policies are not sufficient to comply with the requirements to track and report suspicious orders. Under AmerisourceBergen's deficient policies, it does not hold for review orders that only meet one of the criteria for an order to be deemed suspicious. By limiting the orders even held for review, AmerisourceBergen does not fulfill its obligation to identify orders of interest, much less suspicious orders.

946. Examples of egregious cases identified in an investigation by New York's Attorney General included:

- a. A pharmacy at or above both the 99th percentile in terms of both number of opioid orders and total opioid weight, at which, between 2014 and 2016, more than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges, concerning which AmerisourceBergen reported nearly 200 suspicious order reports in 2013-14, and to which as of 2018, AmerisourceBergen was still serving as this pharmacy's primary opioid distributor;
- b. A pharmacy where, between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or

convicted, including 90% in 2014, and to which Amerisource appears to have only stopped shipping in 2017; and

c. A Bronx pharmacy that exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016), where on average 58% of its opioid prescriptions were paid for in cash (99th percentile), where for three consecutive years (2013 to 2015) approximately half of all opioid scripts were written by prescribers who were later convicted, and which, as of 2018, was still a customer of AmerisourceBergen.

**b. AmerisourceBergen Failed to Effectively Prevent Diversion in Practice.**

947. At all relevant times, AmerisourceBergen failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting AmerisourceBergen's anti-diversion duties, and failed to enforce even the defective policies it had in place.

948. Since the integration of Belco into AmerisourceBergen and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully-trained ground level employees. Since that time, AmerisourceBergen has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing customers.

949. Many of AmerisourceBergen's compliance violations begin with its new customer policy. The process relies heavily on the 590 Form, given that AmerisourceBergen only requests dispensing information from new customers when it already knows of potential issues.

950. Despite the 590 Form being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other AmerisourceBergen procedures relying on reviewing or updating this form, AmerisourceBergen often failed to perform even this baseline screening. Belco Generics customers, for example, regularly completed the 590 Form independently, submitted it to Belco, and were onboarded without receiving a site visit.

951. Disjunction between AmerisourceBergen and Belco has led to many compliance failures. Until system integration in or around November 2015, staff had no systematic way of

identifying dual customers. The lack of an integrated system also meant that thresholds were not coordinated between AmerisourceBergen and Belco. As a result, a dual customer could have high thresholds with both entities and could even be exceeding both thresholds or having both thresholds periodically increased, without detection. In or around April 2013, AmerisourceBergen implemented a policy for dual customers that prevented both AmerisourceBergen and Belco from supplying controlled substances to the same customer, but implementation was spotty, and, in practice, only a small percentage of orders flagged for review were cancelled and even fewer were deemed suspicious.

952. The one area in which AmerisourceBergen has consistently stood out as compared to its major competitors is its unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion. Numerous AmerisourceBergen opioid customers exhibited several common indicators of suspicious activity for multiple years. These flags included:

- a. Scoring above the 90th percentile in the county for opioid order volume;
- b. Scoring above the 90th percentile in the county for total opioid orders;
- c. Scoring above the 90th percentile in the county for oxycodone order volume;
- d. Scoring above the 90th percentile in the county for total oxycodone orders;
- e. Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;
- f. Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;
- g. Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;
- h. Scoring above the 90th percentile in terms of percentage of cash payments; and



- i. Scoring above the 90th percentile in terms of the median MME prescribed per day.

**c. AmerisourceBergen Was Put on Notice of its Wrongful Conduct.**

953. AmerisourceBergen has paid \$16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids. For example, in 2012, it was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.<sup>113</sup>

**3. Anda**

954. Anda was a major distributor nationally, shipping over 1.2 billion MMEs between 2006 and 2014, including 2,6145,300 doses of oxycodone and hydrocodone.

955. Anda recklessly distributed opioids, as its SOM program was deficiently designed and implemented in numerous ways.

956. Anda was cited by the DEA for routinely shipping orders in excess of the monthly threshold it assigned customers.

957. Customer thresholds were routinely increased when a customer placed an order that exceeded the threshold. Examples include (a) obtaining a 3900% increase to 200,000 pills per opioid family per month; (b) approving an increase of 99,999%, which allowed a Nevada customer to “purchase up to unlimited dosage units per month,” and (c) approving a request from a Virginia customer to “make this location unlimited” and removing all thresholds and allowing unlimited purchases. Once adjusted upwards, the new limits would become permanent, even if the reason for the increase was temporary.

958. Anda repeatedly ignored red flags. When Walgreens’s Jupiter, Florida distribution center shut down, Anda became Walgreens’s exclusive secondary distributor of Schedule II controlled substances in 2013. Anda agreed to do so despite the fact that Anda had conducted an audit of Walgreens showing that many Walgreens stores had red flags of diversion. When an Ohio customer

---

<sup>113</sup> Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion>.

was admonished by the DEA for lacking SOM systems, Anda continued to approve huge shipments to the customer. In fact, it repeatedly increased the customer's thresholds from 75,000 units per month per chemical to 200,000 units per month.

959. Anda shipped suspicious orders without reporting them to the DEA. In fact, between 2007 and 2012, Anda did not report a single suspicious order to the DEA.

960. Anda's policy was to clear suspicious orders for a number of standard reasons without actually investigating. The list of acceptable reasons for which suspicious orders could be cleared was vague, thereby allowing clearance for just about any reason. When the DEA told Anda in 2011 that it should start an onsite inspection program, Anda never did. At that time, the DEA told Anda that its Florida distributions, in particular, were a "mess," citing a problem sales representative and many problem pharmacies.

961. Anda's compliance department was severely understaffed. Anda's compliance program had just six employees as compared to the 216 employees in the sales department. This means that each compliance officer would have to review 722 suspicious orders per month to keep up with the workload. Anda's own documents evidence its failed SOM program: in 2011 Anda had 9,624 customers without appropriate due diligence materials to whom Anda was still shipping opioids.

962. Anda's failures with respect to its SOM program are all the more egregious because it knew of the propensity for opioids to be abused and because it had an obligation to take "reasonable measures" to identify suspicious orders and implement procedures to ensure that its opioids were not diverted for illicit use. Instead of focusing on preventing diversion, Anda focused on sales. Anda promoted various opioids to increase its sales numbers while failing to implement an effective SOM program.

#### **4. H.D. Smith**

##### **a. H.D. Smith's Opioid Activity in New York**

963. From 2006 to 2014, H.D. Smith sold 132,241,580 dosage units of hydrocodone and oxycodone in New York. H.D. Smith's excessive distribution was made possible by, and is evidence of, H.D. Smith's failures to comply with its duties under state and federal law.

##### **b. H.D. Smith's Flawed Monitoring Policies and Programs Enabled Opioid Diversion.**

964. Despite public representations to the contrary, H.D. Smith's policies and procedures for monitoring pharmaceutical orders have long been insufficient, which has allowed opioid diversion in New York for an extensive period of time.

965. From 2006 to 2008, H.D. Smith's SOM program was manual, rather than automated. H.D. Smith had two undated and little-used written policies covering suspicious order monitoring. Few employees of H.D. Smith knew these policies existed.

966. Starting in 2006, H.D. Smith began working on an automated compliance system, but this "system" was never really a viable automated system, just iterations and attempts.

967. In or around 2008, H.D. Smith began developing a computer-based suspicious order monitoring program, which H.D. Smith called "CSOMP."

968. CSOMP had multiple flaws that undermined its purpose of detecting and reporting suspicious orders.

969. H.D. Smith's SOM reports, which might have identified suspicious orders, were not reviewed until after the flagged orders had been shipped.

970. CSOMP did not consider opioid order pattern or frequency. H.D. Smith's SOM program permitted automated release of any and all orders by new pharmacies during a 90 to 120 day period, allowing them to "ramp up," even when they exceeded order volume limits. For instance, in an May 21, 2008 internal email, George Fuson ("Fuson"), Director of Corporate Security, wrote to H.D. Smith employees regarding CSOMP enhancements: "You are allowed to release all orders that show up in the system for new accounts for up to 120 days after the start date listed. This will allow

ramp up of new accounts.” When opioid orders neared threshold limits, the orders were still released without further investigation or reporting, allowing the customer to build a high-volume-sales “history.” In fact, in order to avoid reporting a suspicious order to the DEA, H.D. Smith would notify customers when they approached their threshold limits, allowing customers to request threshold increases and avoid triggering thresholds. Additionally, those thresholds for reporting were based on the client’s prior sales. So, if a client spent more, their limit could be reset to that higher point.

971. Issues with CSOMP requiring modifications and fixes to address broken functionality continued until at least February 2015. These issues included stopping only one large controlled drug order at a time for review, while allowing a smaller order for the same customer to be filled while larger order was being reviewed; allowing 448 people within H.D. Smith to release holds in CSOMP; lack of tools to detect orders of unusual frequency or pattern; and multiple accounts assigned to one customer or DEA number, each of which were assigned thresholds (i.e., 3 accounts; 3x the threshold limit for that customer).

972. H.D. Smith was aware of deficiencies with its SOM, and management deliberately tried to hide this knowledge.

973. An H.D. Smith employee with responsibilities for CSOMP monitoring who resigned in February 2015 explained her concerns with H.D. Smith’s SOM system in her exit interview. At the time of the interview, Lori Kirbach stated as a main reason for leaving, **“the company is and has been breaking the law for some time.”** She did not understand why this was being tolerated. Specifically, Ms. Kirbach stated that “CSOMP has not been working correctly since OPUS Go Live and that no one will listen to them when they bring it up. Compliance is releasing orders that they should not be releasing.” She added that “DEA is about two years behind in looking at CSOMP data and it’s only a matter of time before they catch up to us and questions are asked.”

974. Ms. Kirbach also added that her manager “often said not to put certain issues (such as the CSOMP issue) in email so in the event the company is ever sued and the email is produced” other

employees could “deny any knowledge.” She recalled getting her “ass chewed” by her manager, Tom, for putting something in an email that he thought she shouldn’t have.

975. Other H.D. Smith employees have also admitted its SOM program was insufficient. For example, Euson wrote an email on September 28, 2007 regarding a list of suspicious pharmacies he had circulated internally in February 2006 and an updated list of suspicious pharmacies in May 2007. The listed pharmacies had been identified as suspicious by other wholesalers and the DEA due to “excess purchases of controlled substances.” Two of the DEA’s suspicious pharmacies had also been identified by H.D. Smith as one of nine pharmacy customers comprising 80% of H.D. Smith’s Florida distribution of oxycodone. One, Pharmcore, was a customer at the time of the February 2006 email. The other, Pharmacy Express, was set up as a customer in December 2006. According to Euston: “Both have huge and excessive amounts of controlled substance purchases.” He continued, “We will have a hard time explaining to DEA why after we were warned nearly 1 ½ years ago, we continued to sell excessive quantities of CS to these businesses.”

976. Another H.D. Smith employee, P.J. VanderMeersch, Compliance Specialist, wrote in September 2013 about her serious concerns with H.D. Smith’s CSOMP: **“we are absolutely not compliant with Federal Regulations and we know we aren’t.”**

977. As recently as 2014, in a PowerPoint presentation regarding Compliance and Security, the Compliance Department noted the need to develop CSOMP enhancements to meet DEA standards.

978. An H.D. Smith employee wrote an email in July 2014 noting that CSOMP program issues had “resulted in customers receiving products which they were not supposed to.” As a result of these shortfalls, H.D. Smith shipped 17 bottles of oxycodone to one customer who was not supposed to be able to order any.

979. In or around 2014, H.D. Smith hired a new compliance officer and began to create an improved CSOMP program that would comply with applicable laws. However, before any enhancements went into effect, that new compliance officer was terminated in 2016.

980. On May 31, 2016, H.D. Smith rehired their former Vice President of Compliance.

**c. H.D. Smith Participated in Front Groups.**

981. H.D. Smith executives were active in industry groups.

982. J. Christopher Smith, while President and COO, was an active member of HDMA, serving as Co-Chair of its Industry Relations Council. Ron Lanton, Government Affairs Counsel, was a member of HDMA's Government and Public Policy Council. Thomas Doyle, Executive Vice President, Commercial Solutions, was part of HDMA's Specialty & Biotech Distributors Council.

983. Dale Smith, President of H.D. Smith, appears to be an active member of HDA. On HDA's website, he is identified as HDA Vice Chairman and was Chairman and CEO of HDA's Board of Directors and Executive Committee (as of Nov. 2015), having also served on HDA's Government and Public Policy Council and Industry Relations Council.<sup>314</sup>

**d. H.D. Smith's Opioid Settlement**

984. In 2016, H.D. Smith entered into a settlement with West Virginia, agreeing to pay \$3.5 million to resolve an action alleging that the company contributed to the state's opioid addiction epidemic by negligently distributing opioids. H.D. Smith's shipments to West Virginia were so extensive that the House Energy and Commerce Committee wrote to H.D. Smith in 2008, citing DEA data showing sales of 1.1 million hydrocodone doses to Family Discount Pharmacy in Mount Gay-Shamrock, a West Virginia town home to only 1,800 people. That same year, H.D. Smith sold more than 1.3 million hydrocodone and oxycodone to a Sav-Rite Pharmacy in Kermit, West Virginia, a town with a population of 406. Between 2007 and 2008, H.D. Smith also sold 5 million hydrocodone pills to pharmacies in Williamson, West Virginia, where approximately 3,000 people lived. Representatives from both parties were concerned about the volume of opioids H.D. Smith was distributing to West Virginia: "Data provided to the committee by the Drug Enforcement Administration raises . . . questions regarding H.D. Smith's efforts to monitor for, and mitigate, controlled substance diversion in West Virginia." At a May 8, 2018 hearing before the House Energy and Commerce subcommittee,

---

<sup>314</sup> See About, Dale Smith, <https://www.hda.org/persons/dale-smith>; Speaker, IPDC 12-13 Nov. 2015, Brussels, Belgium, Dale Smith, <https://www.hda.org/persons/dale-smith-jr-ipdc>.

H.D. Smith refused to take any responsibility for the massive amounts of opioids it shipped to West Virginia, the state which at the time had the highest overdose rate in the United States. At the time, J. Christopher Smith, former President and CEO, stated, “H.D. Smith conducted itself responsibly and discharged its obligations.” H.D. Smith distributed 1.1 billion oxycodone and hydrocodone pills to West Virginia between 2006 and 2012.

**e. H.D. Smith is Denied Summary Judgment in the MDL.**

985. In 2019, in the MDL proceeding styled *In re: National Prescription Opiate Litigation*, MDL 2804 (N.D. Ohio), H.D. Smith and certain other smaller distributors filed a motion for summary judgment styled “Non-RICO Small Distributors’ Motion for Summary Judgment Based on their *De Minimis* Status (DKT # 1879).” In opposing the motion, the factual record presented by the plaintiffs (two Ohio municipalities) relating to H.D. Smith consisted of a subset of the information enumerated in this subsection. The MDL court denied the motion for summary judgment as to all of the moving defendants, including H.D. Smith.

**5. Henry Schein**

**a. Henry Schein’s Activity in New York**

986. Henry Schein, Inc. was ranked #238 on the Fortune 500 and had global net sales of \$12.5 billion in 2017.

987. Between 2006 and 2014, according to ARCOS data, Henry Schein shipped a total of 2,030,780 opioid dosage units of hydrocodone and oxycodone to New York.

**b. Henry Schein’s Inadequate SOM Program**

988. Henry Schein’s due diligence has been inadequate, falling short of what is required. Henry Schein lacked written SOPs for due diligence obligations until 2012. Henry Schein itself has admitted that it lacked complete due diligence files for all customers until at least 2017. At various times, when an order was flagged, Henry Schein’s due diligence process was limited to sending the customer a one-page questionnaire. No on-site interviews were conducted. Any results of “investigations” were not documented.

989. In August 2013, Henry Schein recognized that it was missing due diligence documents for 27,000 out of approximately 40,000 total customers.

990. An employee testified that, in November 2013, Henry Schein's due diligence documentation was still lacking for 60% of its customers.

991. Henry Schein's SOM program looked for suspicious orders based on deviations in size, failing to account for unusual frequency or pattern. Former DEA chief compliance officer Ronald Buzzeo advised Henry Schein of this deficiency at least as early as 2005.

992. Henry Schein did not report all orders flagged for variations of size, frequency, or pattern to the DEA as suspicious orders until after June 30, 2017.

993. Henry Schein did not report any suspicious orders at all to the DEA for more than a decade. Reports to the DEA, when they occurred, were sent monthly – after orders had shipped – rather than immediately. The DEA recommended Henry Schein changes their practice of reporting monthly in 2005.

994. In February 2011, Henry Schein settled a civil enforcement matter with the DEA, which alleged that Henry Schein failed to design and operate a reliable system that would disclose suspicious orders of controlled substances. Henry Schein paid a fine and allegedly made improvements to its SOM systems.

995. Henry Schein was also issued a Statement of Charges from the Iowa Board of Pharmacy in November 2011.

**c. Henry Schein Is Denied Summary Judgment in the MDL.**

996. In 2019, in the MDL proceeding styled *In re: National Prescription Opiate Litigation*, MDL 2804 (N.D. Ohio), Henry Schein and certain other smaller distributors filed a motion for summary judgment styled “Non-RICO Small Distributors’ Motion for Summary Judgment Based on their *De Minimis* Status (DKT # 1879).” In opposing the motion, the factual record presented by the plaintiffs (two Ohio municipalities) relating to Henry Schein consisted largely of the information enumerated



in this subsection. The MDL court denied the motion for summary judgment as to all of the moving defendants, including Henry Schein.

**K. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.**

997. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

998. The D.C. Circuit recently affirmed that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharmaceuticals*, the court upheld the revocation of the distributor's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Masters Pharmaceutical* was in violation of legal requirements because it failed to conduct necessary investigations before filling suspicious orders. A distributor's investigation must dispel all the red flags giving rise to suspicion prior to shipping a suspicious order. These same duties apply under New York law as well.

999. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups, pressured the DOJ to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the Ensuring Patient Access and Effective Drug Enforcement Act that, ironically, made it more difficult for the DEA to revoke a distributor's license.<sup>315</sup>

---

<sup>315</sup> See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST, Oct. 22, 2016, [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/a6a2bf8e-7f11-11e6-8d13-d7c704ef9fd9\\_story.html?utm\\_term=.2f37833e3e4](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/a6a2bf8e-7f11-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f37833e3e4); Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST,

1000. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

1001. For example, a Cardinal executive claimed that it used “advanced analytics” to monitor its supply chain and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”<sup>316</sup> Given the sales volumes and the company’s history of violations, either this executive was wrong, or, if Cardinal had such a system, it ignored the results.

1002. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiffs now assert. Opioid distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

1003. The wrongful actions and omissions of the Distributor Defendants have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

1004. The Distributor Defendants have abandoned their duties under New York law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

---

(Mar. 6, 2017), [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown-2017-03-06/5846ee60-028b-11e7-b1e9-a05d3c21f1cf\\_story.html?utm\\_term=.700bf2b9455](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown-2017-03-06/5846ee60-028b-11e7-b1e9-a05d3c21f1cf_story.html?utm_term=.700bf2b9455); Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL, Feb. 18, 2017.

<sup>316</sup> Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* WASH. POST (Oct. 22, 2016), [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job-2016-10-22/10e79396-30a7-11e6-8ff7-b6c1998b7a0\\_story.html?utm\\_term=.a5f051722a7a](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job-2016-10-22/10e79396-30a7-11e6-8ff7-b6c1998b7a0_story.html?utm_term=.a5f051722a7a).

**L. Repeated Admonishments and Fines Did Not Stop the Distributor Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion.**

1005. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

1006. In a *60 Minutes* interview, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating, "What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." The interview continued:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

Another DEA veteran stated that these companies failed to make even a "good faith effort" to "do the right thing." He explained, "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."<sup>47</sup>

**M. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.**

1007. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes distributing and dispensing of prescription opioids.

1008. The National Retail Pharmacies' actions and omissions in failing to effectively act to stop diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

---

<sup>47</sup> Transcript, <https://www.linkedin.com/pulse/ex-dea-agent-opioid-crisis-fueled-drug-industry-jennifer>.

1009. The National Retail Pharmacies developed and maintained extensive data on the opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, including in New York. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided other Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to stop diversion, but failed to do so.

1010. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA and must abide by the New York Controlled Substances Act. 21 C.F.R. § 1301.11; N.Y. Pub. Health Law § 3333. Both regulatory schemes require registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a); N.Y. Comp. Codes R. & Regs. tit. 8, § 29.1(b)(1).

1011. This responsibility is not limited to ensuring that the prescription is not, for instance, forged or issued by a practitioner without a valid DEA registration. Rather, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a); *see* N.Y. Comp. Codes R. & Regs. tit. 10, § 80.65 (requiring that prescriptions for controlled substances be "issued for legitimate medical purposes only" and declaring that a prescription issued to an addict outside of the course of professional treatment is not a prescription for purposes of authorizing a pharmacist to dispense controlled substances); *id.* § 910.2(f) (declaring that a prescription for any substance is invalid if "not issued for legitimate medical purposes").

1012. Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity as well as with individual pharmacists. *See* N.Y. Educ. Law § 6808 ("Every owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy.").

1013. Pharmacists are required to ensure that prescriptions for controlled substances are valid and issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Pharmacies are also required to track prescriptions for controlled substances and report suspected abuse and diversion of controlled substances in compliance with federal law and New York regulation. *See* N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.65, 80.110.

1014. The National Retail Pharmacies filled numerous prescriptions containing red flags for diversion without resolving concerns and documenting resolutions, thereby allowing opioids out into the community where they could be diverted.

1015. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

1016. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted. The National Retail Pharmacies failed to contract these entities when faced with evidence of diversion.

1017. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, pharmacists are directed to meet high productivity goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no corresponding metric for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of the National Retail Pharmacies and into communities throughout the country. These policies remained in place even as the epidemic raged.

1018. In addition to acting as dispensaries, the National Retail Pharmacies self-distributed controlled substances to their own retail pharmacies. Distributors of controlled substances such as the National Retail Pharmacies are also required to "design and operate a system to disclose to the

registrant suspicious orders of controlled substances.” 21 C.F.R. § 1301.74(b). A distributor “shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered.” *Id.* Suspicious orders include, but are not limited to, “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

1019. These same requirements apply under New York law. N.Y. Comp. Codes R. & Regs. tit. 10, § 80.110 (requiring persons authorized to possess controlled substances, such as pharmacists, to report actual or suspected diversion of controlled substances); N.Y. Comp. Codes R. & Regs. tit. 8, § 29.1 (defining as unprofessional conduct a “willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession”).

1020. The National Retail Pharmacies failed to design sufficiently robust systems that would effectively identify suspicious orders, failed to halt the shipment of suspicious orders and failed to report suspicious orders.

1021. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that this problem was compounded by the National Retail Pharmacies’ failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into a prescription’s legitimacy, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

1022. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy’s community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual

sales of other drugs.

1023. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures for filling opioid prescriptions.

1024. The National Retail Pharmacies have long been on notice of their failure to abide by the law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal practices surrounding prescription opioid. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiffs allege that based upon the widespread nature of these violations, these enforcement actions are the product of and confirm national policies and practices of the National Retail Pharmacies.

1025. The litany of state and federal actions against the National Retail Pharmacies demonstrates that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and New York laws and regulations that govern the distribution and dispensing of prescription opioids.

1026. On information and belief, from the catbird seat of their retail pharmacy operations and in light of their roles as self-distributors of opioids, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into New York and about the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion. Additional information was provided by news reports and state and federal regulatory actions, including prosecutions of pill mills located near certain pharmacies.

1027. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sales data that

they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

**1. CVS**

**a. CVS Flooded New York With Opioids.**

1028. According to ARCOS data, from 2006 to 2014, CVS distributed 331,060,360 dosage units of oxycodone and hydrocodone in New York. CVS also operated top pharmacy locations. The CVS store in Binghamton was the fifteenth largest dispensary in the state, receiving 6,269,930 dosage units of hydrocodone and oxycodone.

1029. CVS's partner Cardinal Health was the second largest distributor of opioid pills in New York, distributing 811,894,490 dosage units of oxycodone and hydrocodone here between 2006 and 2014.

**b. CVS Failed to Establish an Effective SOM System.**

**i. CVS Knows It Needs an SOM System and Has Existing Capabilities to Create One.**

1030. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of opioids was being sold in New York and in the counties in which Plaintiffs operate. CVS funneled far more opioids here than could have been expected to serve legitimate medical uses and ignored suspicious orders and other red flags of diversion.

1031. CVS was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted, yet did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including reporting suspicious orders and refusing to ship them unless and until due diligence allayed the suspicion.

1032. CVS's public statements indicate that it was aware of its responsibilities to monitor and report suspicious orders of controlled substances. The systems CVS uses for business purposes could have easily been used to identify suspicious orders and practices. However, the extensive list of



settlements detailed elsewhere in this Complaint suggest substantial shortcomings in meeting these responsibilities.

1033. CVS, not any individual CVS store, is the DEA registrant for each CVS pharmacy across the country. CVS renews the DEA licenses for its pharmacies through a “Registration Chain Renewal.” CVS headquarters paid more than \$5 million to renew the licenses of 7,597 CVS locations from October 2013 to December 2016.

1034. CVS CEO Larry Merlo described his company as “America’s front door to health care with a presence in nearly 10,000 communities across the country,” which allowed it to “see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse.”<sup>318</sup>

1035. CVS acknowledged in an article it published in *NEJM* that “[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular.”<sup>319</sup> The DEA agreed, identifying “both pharmaceutical distributors and chain pharmacies as part of the problem” contributing to opioid abuse and related deaths.<sup>320</sup>

1036. The same article noted the advantage the National Retail Pharmacies have in meeting their CSA obligations. Pharmacies can use “aggregated information on all prescriptions filled at the chain” in order to examine “patterns” of opioids and other “high-risk drugs” and target “inappropriate prescribing.”<sup>321</sup>

1037. CVS’s Director of Managed Care Operations, Scott Tierney, testified that CVS’s data vendors were used “for analysis and aggregation of data” and some “consulting services.” CVS would provide the vendors with “prescriber level data, drug level data, plan level data, [and] de-identified patient data.”<sup>322</sup>

---

<sup>318</sup> See, e.g., David Salazar, *CVS Health Unveils New PBM, Pharmacy Efforts to Curb Opioid Abuse*, (Sept. 21, 2017), <https://drugstorenews.com/pharmacy/cvs-health-unveils-new-pbm-pharmacy-efforts-curb-opioid-abuse>.

<sup>319</sup> Mitch Betses & Troven Brennan, *Abusive Prescribing of Controlled Substances - A Pharmacy View*, 369 N. Engl. J. Med. 989, 989 (2013).

<sup>320</sup> *Id.* at 991.

<sup>321</sup> *Id.* at 990.

<sup>322</sup> See Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 \*245–46 (U.S. filed Feb. 22, 2011).

1038. The DEA explained red flags that CVS should be familiar with to carry out its controlled substance responsibilities in a December 2010 meeting with CVS representatives and counsel. In order to ensure that controlled substances were dispensed for legitimate medical purposes, CVS would want to look out for red flags such as: many customers receiving the same combination of prescriptions; many customers receiving the same strength of controlled substances; many customers paying cash for their prescriptions; many customers with the same diagnosis codes written on their prescriptions; and individuals driving long distances to visit physicians and/or to fill prescriptions.<sup>323</sup>

1039. For years after this meeting, the DEA repeatedly advised CVS of the need for a monitoring system and operating procedures to track, investigate, and report suspicious orders. The systems CVS put into place remained deficient. CVS did not report its first suspicious opioid order until February 29, 2012. Nearly two years later, on November 21, 2013, CVS had reported only 7 orders to the DEA across all of its distribution centers and pharmacies in the United States.

#### **ii. CVS's Distribution Network Systems**

1040. CVS distribution centers and outside wholesalers, including its partner Cardinal, supplied opioids to CVS retail pharmacy stores until October 6, 2014. CVS pharmacies placed orders with CVS distribution centers through a CVS central mainframe computer ordering system.

1041. Until at least 2009, CVS relied on the gut instincts of human pickers and packers of the drugs in distribution centers – workers responsible for pulling items off distribution shelves for delivery to pharmacy stores – to identify “really big” orders. CVS did not train pickers and packers how to identify unusual orders by size, frequency, or patterns. Until August 2013, CVS did not have even have written policies, procedures, or protocols regarding obligations of pickers and packers. This was not an effective SOM system.

1042. In 2007, CVS began working on a Standard Operating Procedure Manual (“SOP”) to address controlled-substances compliance, including SOM. For years thereafter no such manual or

---

<sup>323</sup> See Declaration of Joe Rannazzisi, *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012).

SOM had been completed. Until August 2010, CVS's internal documents indicated CVS was "still in the process of writing the suspicious order monitoring section of this standard operating procedure."

1043. During this time, CVS employed a CVS DEA compliance coordinator. The employee holding that title from 2008 to 2014 has stated that her title was only for reference in SOPs and not her real job. She had nothing to do with SOM monitoring other than updating the SOP.

### **iii. CVS's Automated System for SOM**

1044. In 2009, CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. Flagged orders produced an Item Review Report ("IRR"). For several years, CVS manipulated the IRR algorithm to be less sensitive and to flag fewer orders for investigation. CVS believed that the SOM was producing too many IRRs for orders CVS believed were "not suspicious on their face." IRRs were the primary SOM process. If an order was not flagged as suspicious under the IRR system, there was no due diligence of that order.

1045. CVS learned in 2010 that its SOM algorithm was also deficient because it only monitored by drug, not active ingredient. This meant that if a drug's name or description changed, historical data would be lost, and the system could not determine whether orders exceeded or diverged from prior volumes or patterns.

1046. CVS's SOM algorithm also failed to consider store pharmacy orders from outside vendors. The SOM did not track how many opioids a CVS pharmacy ordered from Cardinal, for example, alongside any orders placed directly with a CVS distribution center. CVS knew this was a problem and that stores engaged in this practice to stay below reporting thresholds. Pharmacies could also circumvent reporting thresholds by placing telephone orders with outside vendors. This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

1047. While CVS could now report that it had developed an automated SOM system, it neglected to provide written instructions to its employees for how to perform critical reviews of the IRRs until February 29, 2012.

1048. In 2012, CVS also created guidelines explaining “red flags” or cautionary signals CVS pharmacists should look for to prevent diversion and ensure controlled substance prescriptions were issued for legitimate medical purposes. However, CVS failed to use data available at the corporate level to assist pharmacists with evaluating these diversion red flags.

1049. In July 2013, internal e-mails reflected that CVS’s primary tool for investigating suspicious orders relied on data that was months or even years old and made any analysis, “for the most part, irrelevant and pointless.”

1050. In March 2014, CVS implemented a new SOM system in the Indianapolis distribution system. System data feed issues created inaccuracies in the SOM historical data. A risk analysis of the new system determined, in June 2014, that the risk level was high due to: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; and lack of clarity in how the new SOM system was identifying suspicious orders.

**iv. CVS Implemented an Integrated Systems to Track Profits.**

1051. Although CVS failed repeatedly to implement an effective SOM system years after being alerted to the need to do so, CVS did implement a system related to its own profits by 2010.

1052. By 2010, CVS could not track the accuracy of pharmacies or customer safety metrics, but it had found a way to track pharmacists’ speed and volume. Pharmacists’ bonuses were tied to the number of prescriptions they filled; opioid prescriptions were included in this tally until 2013. CVS still puts profits and profitability over customer safety and prescription accuracy with pharmacists in 2020 describing CVS as the “most aggressive chain in imposing performance metrics.”<sup>324</sup>

---

<sup>324</sup> Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, N.Y. Times, (Jan. 31, 2020), <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>.

**c. CVS Worked with Other Defendants to Increase Profits and Disseminate False Information.**

1053. CVS understood that in order for Cardinal and McKesson to meet their due diligence obligations under the CSA, they would need access to CVS's dispensing information. CVS refused to provide dispensing information about doctors or patients unless it was requested by the DEA.

1054. Prior to 2013, Cardinal and McKesson performed due diligence differently for CVS than for other pharmacies. Instead of distributors contacting or visiting CVS stores, as with other pharmacies, they contacted CVS's loss prevention offices at corporate headquarters. This meant that CVS controlled all "due diligence investigations" of its opioid orders. CVS prevented distributors from independently determining appropriate order thresholds for opioids at CVS stores, reserving the right to adjust threshold quantities and percentages to values CVS deemed appropriate.

**d. Multiple Enforcement Actions Against CVS Confirm Its Compliance Failures.**

1055. CVS is a repeat offender; the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require and violating their recordkeeping and dispensing obligations. The following examples are illustrative rather than exhaustive.

1056. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008 to 2012, CVS stores and pharmacists in Maryland violated their duties under the CSA by filling prescriptions with no legitimate medical purpose.<sup>125</sup>

1057. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain

---

<sup>125</sup> Press Release, U.S. Attorney's Office Dist. of Md., United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (Feb. 12, 2016), <https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled>.

opioid drugs.<sup>326</sup>

1058. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.<sup>327</sup>

1059. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."<sup>328</sup>

1060. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.<sup>329</sup>

1061. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for

<sup>326</sup> Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), <https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state>.

<sup>327</sup> Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

<sup>328</sup> Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

<sup>329</sup> Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), <http://www.expressnews.com/business/local/article/H-E-B-CVS-fined-over-prescriptions-5736554.php>.

improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.<sup>330</sup>

1062. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.<sup>331</sup>

## **2. Walgreens**

### **a. Walgreens Flooded New York With Opioids.**

1063. Acting as both a distributor and a retail pharmacy chain, Walgreens self-distributed opioids to its own individual Walgreens pharmacies. Walgreens has an abundance of information as to exactly how many pills were distributed to and dispensed from which retail pharmacies. In fact, Walgreens and the other National Retail Pharmacies, by virtue of their integrated structures, likely had more and better information as to the circumstances associated with the retail distribution of opioids than the large independent distributors.

1064. According to ARCOS data, Walgreen's distributed 247,343,080 oxycodone and hydrocodone pills to its retail pharmacies in New York between 2006 and 2014. The same data shows one Walgreens store in Selden dispensing 7,443,000 pills during this period.

### **b. Walgreens Designed and Implemented an Entirely Inadequate SOM System.**

1065. Walgreens collected the data on suspicious orders in a Suspicious Control Drug Order report. To generate this report, Walgreens used two different formulas: one formula from (at least) 1998 to 2007 and another formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be

---

<sup>330</sup> Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NEWSOK (May 3, 2015), <http://newsok.com/article/5415840>.

<sup>331</sup> Press Release, U.S. Attorney's Office W. Dist. of Okla., *CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act*, U.S. Dep't of Just. (Apr. 3, 2013), <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled>.

suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

1066. In a letter of admonition, the DEA reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)" though Walgreens failed to examine anything other than the size of an order. When Walgreens did update its program in 2007, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use a "three times" formula.

1067. Walgreens failed to perform any reasonable due diligence on thousands of orders identified as "suspicious" and instead shipped the orders without meaningful review.

1068. In September 2012, the DEA issued an immediate suspension order ("ISO") for Walgreens's Schedule II distribution center in Jupiter, Florida, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that the distribution center failed to comply with DEA regulations that required it to report suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. According to the DEA, "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

1069. In the ISO, the DEA specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law about Walgreens's suspicious order monitoring system—applicable across Walgreens's operations:

"[Walgreens's] practice with regard to suspicious order reporting was to send to the



local DEA field office a monthly report labeled “Suspicious Control Drug Orders.”

“[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports.”

“Upon review of an example of the Suspicious Control Drug Order report for December 2011, [Walgreens’s] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico.”

Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: “This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy’s location, the population it serves, or the number of other pharmacies in the area.”

“As made clear in 21 C.F.R. § 1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order’s legitimacy is concluded.”

“DEA’s investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. § 1301.74(b). 21 C.F.R. § 1301.74(b).”

“DEA investigation of [Walgreens’s] distribution practices and policies . . . demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. 55 823(b)(1 and (e)(1). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein.”

“[DEA’s] concerns with [Walgreens’s] distribution practices are not limited to the six

Walgreens pharmacies [for which DEA suspended Walgreens's dispensing registration]."

**c. Walgreens Knew Its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.**

1070. There is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it to the DEA. Walgreens did not perform due diligence reviews on any of the orders listed on a report before shipment.

1071. Moreover, in September 2007, three senior Walgreens employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Jerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact."

1072. In a December 2008 Internal Audit of its Perrysburg (Ohio) Distribution Center, Walgreens acknowledged systemic and longstanding failures in the systems surrounding DEA compliance:

In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:

DC-wide:

- pseudoephedrine reporting requirements and inventory maintenance
- suspicious controlled drug order processing and reporting
- controlled drug reporting, specifically receiving record information
- lack of formalized CII controlled substance policies and procedures.

1073. The Internal Audit continues, "Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA

upon discovery.” It also notes that while “Walgreens produces monthly Suspicious Controlled Drug Orders-report,” the audit team recommended discussions continue across multiple departments within Walgreens regarding “reporting suspicious control drug orders” and an “Updated Suspicious Control Drug Order Identification Methodology,” with an “Estimated Completion Date for the New Reporting” of “June 30 2009.” The audit also underlined Walgreens’s lack of urgency in addressing the problems, indicating that the next “Cross-Functional Meeting” to address the “Updated Suspicious Controlled Drug Order Identification Methodology” would not occur for more than five months.

**d. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.**

1074. The only review of the orders identified by Walgreens’s distribution-center-level procedures was calling the pharmacy to make sure the order had not been entered in error. This procedure was not intended to detect suspicious orders.

1075. In March 2008, Walgreens finally formed a five department “team” to “begin creating” a SOM program. The new SOM program was not piloted until August 2009, and, even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in bits and pieces, be rolled out chain-wide. From that point it took several more years to fully implement.

**e. Even As It Rolled Out Its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.**

1076. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens’s primary focus, the SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing with outside distributors like Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside distributor even if the order had already been rejected by the new SOM system.

1077. Further, although the new SOM algorithm identified more than 389 pages of

suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its “three times” formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA “on a monthly basis.” This “discrepancy” prompted an internal email from an employee in Walgreens’s Loss Prevention Department to Walgreens’s Vice President, Distribution Centers and Logistics, suggesting that “the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that “we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week” and asked if his department had “a resource available” to assist. An email in response “recall[ed] the old paper report as being inches thick” and an instruction “in 1985 not to review or contact anyone on the data,” and inquired, among other things, “Who from your group has been reviewing the data collected for the past twenty-five years?” and “At present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?”

1078. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens’s new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious nor were they halted for review. The DEA found that Walgreens’s policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to orders, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is “to provide investigators in the field with information regarding potential illegal activity in an expeditious manner.” 72 FR at 36501.

1079. Walgreens’s post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were “marked suspicious” by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens

failed to adequately staff the program and to train its employees regarding its requirements.

1080. One example of the sorts of information that was available and considered, but not acted upon, is found in emails from January 10-11, 2011 between a Walgreens DC employee and Barbara Martin, an employee identified by Walgreens as being one of two employees primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The DC employee notes that “several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis.” The DC employee continued, with respect to a single store, “we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don’t know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?” Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per week, stating, “I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles).” Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he “may be able to shed some light on the subject.” Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

1081. In the ISO regarding the Jupiter DC, the DEA specifically found of the orders that were the subject of these email exchanges that “[b]ased on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy.” The DEA further found that Walgreens “failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels.” The DEA noted that “[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.”

1082. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing “new changes” to “enhance” its SOM program.

1083. In December 2012, the further enhanced SOM system flagged “14,000 items that the stores ordered across the chain that would have to be investigated” before they could be shipped. Walgreens did not have sufficient resources to timely review these orders. Walgreens noted that “[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances.” At the time these 14,000 orders were flagged, Walgreens Rx Integrity Team was comprised of fewer than five people. Even at its height, Rx Integrity had only eleven employees.

1084. As described below, Walgreens has admitted to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of Walgreens’s Pharmaceutical Integrity Managers in August 2013 explained:

The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override . . . . The purpose for this is to ensure we have performed adequate review before sending in additional inventory.

The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEA’s investigation of Walgreens.

1085. Yet, even in 2013, orders being flagged as suspicious for review before shipment were “a week old” before they made it to the review team, often “ha[d] already been shipped,” and were not being reported.

1086. Walgreens never equipped its distribution operations to properly monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that “while the financial impact of no

longer . . . [self-distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses.”

**f. Walgreens Failed to Put in Place Adequate Policies to Guard Against Diversion at the Pharmacy Level.**

1087. Although Walgreens purported to have in place “Good Faith Dispensing” (“GFD”) policies for many years, it failed to meaningfully apply these policies or to train employees in its retail pharmacies to identify and report potential diversion.

1088. Despite knowing that prescribers could contribute to diversion and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens’s GFD explicitly instructed pharmacists who “received a questionable prescription” or otherwise were “unable to dispense a prescription in good faith” to “contact the prescriber” and, if “confirm[ed]” as “valid” by the prescriber, to then “process the prescription as normal.” Further, though Walgreens’s policies listed a handful of “questionable circumstances,” such as “increased frequency of prescriptions for the same or similar controlled drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed,” it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber “confirm[ed]” the prescription as “valid.”

1089. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal or when other suspicious circumstances are present.

1090. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all “Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances,” requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide “compliance program to detect and prevent diversion of controlled substances as required by the . . . (CSA) and applicable DEA regulations.” Pursuant to the MOA, the “program shall include procedures to identify the common



signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills” as well as “routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA.” Further, Walgreens was required to “implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations.”

1091. As with distribution, Walgreens failed to allocate anywhere near the resources necessary to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were “challenged to get into the stores” and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a “high number of stores,” and their time was consumed with “people processes, business planning, market and district meetings,” such that supervision in store was being handled informally by “community leaders” who have “limited formal authority.”

1092. Unsurprisingly, compliance with GFD has been poor. After a 2015 internal audit, Walgreens concluded: “Results were unfavorable.” Fewer than 60% of stores were complying with GFD policies with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months.

**g. Walgreens Assumed Greater Responsibility for Controlling Against Diversion by Discouraging Outside Vendors from Exercising Their Own Oversight.**

1093. The “Big Three” wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies such as Walgreens. An internal Cardinal document for



example, stresses that “certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal or to make certifications” and that large, national chains can “take their billions upon billions of dollars in business to any wholesaler in the country.”

1094. Thus, for example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would “minimize the disruption” to retail chains and that they would “work together” with the pharmacies “to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt” business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such “early warnings” were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by “flagging the stores at 75%,” it could “avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA.”

1095. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen Drug Company.

1096. By 2017, Walgreens accounted for 30% of AmerisourceBergen’s revenue.<sup>32</sup>

1097. AmerisourceBergen was similarly deferential, allowing Walgreens to “police their own orders and block any order to [AmerisourceBergen (“ABC”)] that would exceed ABC’s threshold thus triggering a suspicious order being sent to DEA from ABC.” Additionally, when AmerisourceBergen received orders from Walgreens “outside the expected usage,” Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using “soft blocking.” Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its “order monitoring program” with

---

<sup>32</sup> As a part of its distribution agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen’s Co-Chief Operating Officer sits on the AmerisourceBergen Board of Directors.

Walgreens and provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.

**h. Walgreens Failed to Maintain Effective Controls Against Diversion in New York.**

1098. Walgreens violated the standard of care for a distributor and dispenser by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion; and (e) refrain from dispensing opioids for other than legitimate medical purposes.

1099. The volume of opioids Walgreens shipped into and dispensed in New York was so high as to put it on notice that that not all of the drugs being ordered would be used to fill prescriptions for legitimate medical uses.

1100. Yet, upon information and belief, Walgreens made no or virtually no Suspicious Order Reports for New York between 2007 and 2014. Instead, Walgreens funneled far more opioids into New York in general, and Erie County in particular, than could have been expected to serve legitimate medical use, while ignoring other red flags of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), should have alerted Walgreens to potential diversion of opioids.

1101. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

1102. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens

stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion. Walgreens chose not to do so.

1103. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of indicia of diversion such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug “cocktails,” known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

1104. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids or to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

1105. Upon information and belief, Walgreens failed to adequately analyze and address its opioid sales relative to: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy’s community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

1106. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

**i. Walgreens’s Performance Metrics Put Profits Before Safety.**

1107. In connection with the DEA’s investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone. As the DEA’s September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

In July 2010, Walgreens’s corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11

page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "busiest store in Florida" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about 1 a day. Are we turning away good customers?"

1108. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business," i.e., dispense more Schedule II controlled substances. This focus on increasing controlled substance dispensing – including opioids – continued even after the DEA investigation and \$80 million fine. For example, in 2014, the RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone... hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol... [and] alprazolam."

1109. Walgreens emphasized in its policies for pharmacists and pharmacy managers: "The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales." A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you." When considering high Schedule II dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

1110. Walgreens also lobbied against imposition of caps or limits on the volume of prescriptions a pharmacist may fill.

**j. Walgreens Entered Into Joint Ventures that Further Undermined Its Outside Vendors' Incentive to Conduct Due Diligence While Increasing Its Own Access to Information.**

1111. The merger of Walgreens and AmerisourceBergen began in 2012 when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain “purchasing synergies” from Walgreens through the companies’ relationship.

1112. Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into the “corporate guidelines” that Walgreens’s pharmacists were “expected to follow” when it came to the dispensing of prescription opioids.

1113. Starting in at least 1999, Purdue sponsored Walgreens’s Pharmacy continuing education programs designed to encourage stores to “get on the Pro Pain Management Band Wagon.” Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented *Pain Management for the Pharmacist*. At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a “full-service” pain management pharmacy. This service included providing a list to physicians’ offices of all CII they had in stock (and they had everything), accepting “verbal orders” for Class II analgesics prior to presentation of the original prescription at the store to decrease “waiting time,” allowing partial fills on CII prescriptions in terminal patients, and accepting after hours “emergency CII prescriptions” without a hassle. Purdue praised the pharmacist’s actions as “fantastic”.

1114. Walgreens’s use of pro-opioid continuing education continued as the opioid crisis grew. For example, Walgreens’s Market Director of Pharmacy Operations recommended that Walgreens’s District Managers and Pharmacy Supervisors attend a continuing education program titled *The Pharmacists’ Role in Pain Management: A Legal Perspective*, which was available on-line at RxSchool.com. This program was one in a long line of pharmacist “education” programs, or CEs, that

Purdue developed as part of its strategy to disseminate “a new school of thought” about opioids. Through these programs, Purdue and the National Retail Pharmacies disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists’ supposed “misunderstanding” about pain patients and the practice of pain management. Purdue took what it called an “aggressive role” in educating Walgreens’s pharmacists on pain management issues.

1115. Walgreens’s Market Director of Pharmacy Operations also recommended an Endo-sponsored continuing education program, *Navigating the Management of Chronic Pain: A Pharmacist’s Guide*. This CE disseminated manufacturer messaging designed to broaden the market for opioids. For example, it stated “according to most reports, approximately 30% of the population lives with chronic pain” and citing, *inter alia*, another CE presentation sponsored by APS. It also claimed that “most opioid adverse effects can be managed with careful planning and patient education.” It went on to discuss “fears and prejudices” related to addictive behaviors that “unnecessarily limit” opioid use, described as “opiophobia” which the piece claimed was the result of “misunderstandings regarding the concepts of addiction, physical dependence, and tolerance.”

1116. One of the presenters for this Endo-sponsored CE was Kenneth C. Jackson. Mr. Jackson was also a frequent speaker and KOL for Purdue. In addition, he co-authored a Purdue-sponsored CE program, *Use of Opioids in Chronic Noncancer Pain*. Released in April 2000, it was designed to eliminate “misconceptions about addiction, tolerance and dependence.”

1117. Walgreens also presented the video, *The Pharmacist’s Role in Pain Management - A Legal Perspective*, at mandatory meetings for pharmacy managers. This CE was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreens’s pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for AAPM, acted as a KOL for Purdue, and was described by Purdue as “a pain patient who takes opioids.”

**k. Multiple Enforcement Actions Against Walgreens Confirm Its Compliance Failures.**

1118. Walgreens has been penalized for serious and flagrant violations of the CSA. Indeed,

Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations in Florida, New York, Michigan, and Colorado, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.<sup>333</sup>

1119. The Florida operations at issue in this settlement highlight Walgreens's egregious conduct. Walgreens's Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.<sup>334</sup> This included, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period

1120. They increased their orders over time, in some cases as much as 600% in the space of just two years. Yet Walgreens's corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with drug laws or the health of communities.<sup>335</sup>

1121. Walgreens's settlement with the DEA stemmed from the DEA's investigation into Walgreens's distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Walgreens's corporate headquarters pushed to increase the number of oxycodone sales to Walgreens's Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by

---

<sup>333</sup> Press Release, U.S. Attorney's Office S. Dist. of Fla., Walgreens Agrees to Pay a Record Settlement of \$80 Million for Civil Penalties Under the Controlled Substances Act, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled>.

<sup>334</sup> Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.<sup>336</sup>

1122. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).<sup>337</sup>

1123. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.<sup>338</sup>

### 3. Walmart

1124. As an example of the magnitude of Walmart's self-distribution and dispensing of opioids, one can look to Genesee County, New York. According to data from the ARCOS database, between 2006 and 2014, Walmart distributed 2,717,000 dosage units of oxycodone and hydrocodone to the Walmart pharmacy there. The volume of opioids Walmart shipped into Genesee County was so high that Walmart must have known that the orders were suspicious. Walmart then dispensed 2,814,330 pills from the same Walmart pharmacy location;<sup>339</sup> the volume of prescriptions being filled, let alone any of their characteristics, should have informed Walmart that prescriptions being filled were not for legitimate medical uses, were issued outside the usual course of professional practice, or both.

1125. From 2012 to 2018, Walmart was the largest distributor of oxycodone, hydrocodone, and hydromorphone in the United States.

---

<sup>336</sup> *Id.*

<sup>337</sup> Felice J. Freyer, *Walgreens to pay \$200,000 settlement for lapses with opioids*, BOSTON GLOBE, Jan. 18, 2017, <https://www.bostonglobe.com/metro/2017/01/18/walgreens-agrees-better-monitor-opioid-dispensing/q0B3FbMo2k3wPt4hvmTQrM/story.html>.

<sup>338</sup> *Id.*

<sup>339</sup> As discussed below, the difference is accounted for by the fact that Walmart allowed its pharmacies to order opioids both from Walmart and from outside distributors, effectively allowing pharmacies to circumvent the meager limits Walmart put in place.



1126. Because Walmart self-distributed opioids to its own pharmacies, Walmart had access to data unavailable to independent distributors, but failed to use that data to fulfill its obligations to identify, investigate, halt, and report suspicious orders. Such data included information about prescriptions that pharmacists had refused to fill, its pharmacists' knowledge of pill mill prescribers, and its ability to track prescriptions paid for in cash or filled for individuals who lived considerable distances from their prescriber or from the Walmart pharmacy filling the prescription. Such data was in addition to the data about individual pharmacies available to any distributor.

1127. Walmart could have, but did not, use its "big data" capabilities to detect suspicious orders. Instead, Walmart used sophisticated data analysis only to improve efficiency and generate greater profit.

1128. And even when Walmart did investigate an order to determine if it was suspicious, Walmart failed to document the investigation, thereby violating its obligations under federal and state law and deliberately depriving itself of information it could have used to detect diversion from associated with particular pharmacies.

1129. Walmart and Sam's Club pharmacies used McKesson and AmerisourceBergen as back-up distributors for controlled substances. Although Walmart pharmacies could order additional opioids from these distributors, Walmart failed to account for these orders in its SOM program. This failure is even more egregious because Walmart, as the corporate owner of each of its pharmacies, had or should have had the data necessary to determine what orders for opioids were placed with these outside distributors.

1130. Walmart's SOM was so deficient that Walmart failed to report at least hundreds of thousands of suspicious orders. From June 26, 2013 to November 29, 2017, Walmart sent its pharmacies 15.2 million orders of Schedule II controlled substances and Schedule III narcotics. In that time, it reported only 204 suspicious orders. By comparison, McKesson, when receiving orders from Walmart pharmacies, reported more than 13,000 suspicious orders in the same period.

1131. Walmart knew that its deficient SOM program and its regular habit of shipping orders of interest before determine whether or not they were suspicious posed a great risk of diversion. Indeed, Walmart's Senior Manager of Logistics wrote in an August 2014 email:

The alternative to pulling the order back is to simply continue to follow the process we have today. We can add further evaluation of orders after shipment but, if we see an issue that suggests that product shouldn't have been shipped, we just leave it at the store and let it enter the market. Given the choices, [having the store] ship . . . the product back feels like the more socially responsible approach, but the [Distribution Center] will do whatever leadership wants them to do.

1132. Prior to November 2010, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

1133. Walmart has claimed that its hourly employees and associates monitored the orders they were filling at Walmart Distribution Centers for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day. Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

1134. Upon information and belief, Walmart can produce no written evidence that any such instructions were given to Walmart associates, no evidence that the training necessary to implement such a procedure had been conducted, and no evidence that anyone was actually alerted about an unusual order or performed any follow up inquiry.

1135. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart has suggested that its associates' subjective judgment based on their "knowledge and experience" as distribution center employees was sufficient. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to November 2010. Moreover, Walmart continued to use such employees to conduct the required monitoring for suspicious orders despite their lack of training.

1136. Beginning in November 2010, Walmart began to require certain employees to review

a monthly “control drug stock exception report.” This report, produced after the controlled substances had already been shipped, identified pharmacies whose controlled substances orders exceeded 3.99% of their total orders.

1137. This policy failed to comply with Walmart’s obligations because it could not identify orders of unusual frequency or pattern nor could it identify individual unusually large orders. This policy also failed to halt shipment of any suspicious orders.

1138. In attachment to an email sent by Walmart’s then-Director of Compliance on June 12, 2014, Walmart noted that it might need to modify its SOM system “to help Walmart avoid DEA enforcement as a result of non-compliance with 21 CFR 1301.74(b).”

1139. At some point after November 2010, Walmart implemented a program establishing uniform numeric thresholds for the number of bottles of controlled substances individual pharmacies could order without taking into account characteristics that might warrant lower numbers, such as the size of the community or the presence of nearby competitor pharmacies. The system purported to flag orders for more than 20 bottles of a Schedule II substance; for more than 50 bottles of a Schedule III, IV, or V substance; or for 30% more than the rolling four-week average (only if a store ordered 11 bottles or more). Walmart had no reason for selecting 50 bottles as the same threshold for drugs of widely varying abuse potential. The policy also failed to identify orders of unusual frequency or pattern because it was only designed to evaluate the size of orders.

1140. At this time, the system used to monitor for suspicious orders was called Reddwerks. This system was not designed as an SOM system, but was instead an order fulfillment system that tracked orders placed by pharmacies and shipments from distribution centers to pharmacies.

1141. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. On the contrary, upon information and belief, Walmart *never* reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart would simply cut the order to the 50-bottle threshold and ship it.

1142. This practice continued until mid-2012, when Walmart implemented “hard limits” on opioid orders. Under this approach, weekly orders of Oxycodone 30mg (“Oxy 30”) were automatically reduced to 20 bottles. Still, Walmart failed to report orders over that threshold to the DEA.

1143. Walmart knew that it violated its obligations to prevent diversion by failing to report orders that Walmart reduced to its internal threshold before shipping. In a February 2015 meeting, DEA diversion investigators actually told Walmart this. Nevertheless, Walmart continued to ship cut orders without reporting the original suspicious order until at least November 29, 2017.

1144. Despite the laxity of this policy, Walmart did not even apply it consistently. On at least 216 separate occasions between June 2013 and July 2015, Walmart shipped more than 20 bottles of Oxy 30 to an individual pharmacy within a single week. Because roughly half of these orders were placed to six individual pharmacies, Walmart had information suggestive of diversion in these locations; it thus had an obligation to report to these orders to the DEA. Walmart, of course, failed to do so.

1145. And even if Walmart had consistently applied this policy, it would still have been insufficient because it was based on the number of bottles, not the number of pills. Walmart pharmacies exploited this loophole by ordering larger bottles. Walmart was well aware of this deficiency. In an October 11, 2013 memorandum, the General Manager of Distribution Center 6046 in Williamsport, Maryland highlighted a store that had switched from 100-count bottles to 1000-count bottles and concluded that Walmart needed to switch from flagging bottles to flagging pills. Walmart did not begin to do so until at least August 2015.

1146. Another deficiency of Walmart’s threshold program was that it worked only by National Drug Codes (“NDCs”) rather than by controlled substance. If two different manufacturers produce a pill with the same dose of the same drug, these two pills will have separate NDCs. Thus, Walmart pharmacies could exceed the thresholds by ordering the same product made by two different manufacturers. They did this on 146 occasions for Oxy 30 and at least 1,500 times for other Schedule II controlled substances.

1147. Walmart also monitored weekly orders of more than 20 bottles of Schedule II controlled substances other than Oxy 30. This “Over 20 Report” was provided to the corporate office in the morning, and, if nothing was done by mid-afternoon, the orders were filled and shipped. In many cases, orders on the report were only investigated in a cursory fashion or never even investigated at all before being shipped despite Walmart classifying them as orders of interest.

1148. In an attempt to repair deficiencies in its SOM, Walmart modified its policy in July 2014 to require evaluation of individual orders by identifying orders of interest and then investigating them to determine when they were suspicious. This policy was still deficient because it relied on Reddwerks, which could only identify orders of unusual size. Walmart was aware of this deficiency as early as October 2014.

1149. Walmart also ignored other signs of diversion beyond the size, frequency, and pattern of orders. In a number of cases, Walmart pharmacists alerted compliance personnel that they were receiving prescriptions issued by pill mills and that they were witnessing first-hand evidence of diversion. For instance, despite several notifications from pharmacists at Store 5654 in Tampa, Florida that a particular prescriber was “questionable” and had a pattern of prescribing large quantities of opioids, Walmart failed to report any suspicious orders or limit shipments to that store.

1150. Walmart knew that its monitoring program was insufficient to fulfill its obligation to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. Walmart further acknowledged in 2014 that it had “no process in place” to comply with government regulations and that this created the “severe” risk of “financial or reputational impact to the company.” It was not until late 2014 that Walmart’s written policies and procedures required orders of interest to be held and investigated.

1151. In 2015, Walmart made some modifications to Reddwerks in an attempt to improve its SOM. However, in doing so, Walmart used a statistical methodology that an outside contractor, Mu Sigma, had identified as flawed. In fact, Mu Sigma had proposed a replacement SOM for

Reddwerks that Walmart rejected due to cost, despite the fact that Mu Sigma's bid amounted to 0.0007% of Walmart's operating revenue.

1152. Walmart's methodology was flawed, in part, because the thresholds Walmart used to determine whether a pharmacy's orders required investigation were based on the pharmacy's prior orders over the previous fifty-two weeks. These orders, of course, were those allowed under the Reddwerks system which, as discussed above, were often already excessive. Therefore, Walmart's new system would fail to detect certain suspicious orders.

1153. Moreover, Walmart set an artificial threshold of 2,000 dosage units for controlled substances. Any order below that threshold was deemed non-suspicious. As a result, a pharmacy that typically ordered very small quantities of a controlled substance could radically increase the size of its order (thereby becoming very large for that pharmacy) without triggering review.

1154. Walmart also continued its practice of cutting orders to the threshold without reporting the original suspicious order to the DEA. On information and belief, this practice continued until at least November 29, 2017.

1155. At times, Walmart would place certain pharmacies on remediation plans designed to limit their orders of controlled substances. Despite these plans, Walmart would still ship orders that exceeded the thresholds established in the plans. For instance, during a two-month remediation period in which Store 2530 was limited to 50 bottles of buprenorphine HCl 8mg per week, Walmart twice shipped orders exceeding that amount without making any report to the DEA.

1156. Walmart pharmacies in New York dispensed staggering quantities of opioids. For example, one Walmart pharmacy in Oneonta dispensed 2,869,700 dosage units of oxycodone and hydrocodone from 2006 to 2014, the years for which ARCOS data is available. This was enough for 21 pills per person for year for individuals living within 5 miles of the pharmacy.

1157. Walmart imposed requirements and restrictions on pharmacists to encourage rapid filling of prescriptions of all types without adequate time for investigation. One result was that Walmart pharmacists filled numerous prescriptions with red flags that pharmacists knew or should

have known were almost certainly invalid. These red flags included: (1) combinations of opioids that should not be used together (such as multiple immediate-release opioids, multiple dosages of the same immediate-release opioid, or an immediate-release opioid alongside methadone); (2) commonly abused combinations of opioids with non-opioids (including the “trinity” of an opioid, a benzodiazepine, and carisoprodol); (3) repeated prescriptions for very high dosages and quantities of opioids (including, on 16 separate occasions giving one customer enough medication to take 93 opioid pills per day); and (4) requests to fill Schedule II prescriptions earlier than would be necessary if the drugs were being consumed on schedule.

1158. When Walmart pharmacists suspected diversion based on an individual prescriber’s practices, pharmacists could not refuse to fill all controlled-substance prescriptions from that provider. Instead, they had to refuse each prescription individually by “fill[ing] out a form that could take 20 minutes, a bureaucratic hurdle that pharmacists sought to avoid because they were under pressure to fill prescriptions quickly.”<sup>340</sup> In fact, a 2011 document from Walmart Regulatory Affairs regarding the “Proper Prescriber-Patient Relationship” stated: “Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill.”<sup>341</sup> Walmart only began to allow blanket refusals to fill in 2017.

1159. In addition, Walmart always had the ability to “centrally block” problematic prescribers across all Walmart and Sam’s Club pharmacies, but did not establish a procedure to do so until 2017. In the “Practice Compliance” document describing this policy, Walmart admitted that it has information about prescribing practices that is not available to individual pharmacists:

While pharmacists are in the best position to determine whether individual prescriptions are appropriate, **additional information may be obtained that is not available to our pharmacists.** Therefore, in certain situations, a prescriber may be

---

<sup>340</sup> Jesse Fisinger & James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (Mar. 25, 2020), <https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment> (hereinafter, “Fisinger & Bandler”).

<sup>341</sup> *Id.*

identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

1160. One internal email showed that in response to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, Brad Nelson, wrote, "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time."<sup>342</sup>

1161. Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions filled and the amount of profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled. As a result, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review prescriptions and conduct the appropriate due diligence. In combination with low staffing, this led pharmacists to complain that these conditions did not "allow time for individual evaluation of prescriptions."

1162. Because Walmart also refused until 2017 to allow blanket refusals to fill or central blocks, Walmart created a situation in which inappropriate dispensing of opioids was inevitable. It was simply impractical for Walmart pharmacists to simultaneously comply with Walmart's demand for speedy filling of prescriptions and its demand that each prescription from a pill mill doctor be separately rejected and documented on a refusal-to-fill form. As noted by one Walmart pharmacy manager explained in a February 6, 2015 email, if the pharmacists individually rejected each prescription from a pill mill doctor, "that is all we would do all day long."

1163. These systemic issues are reflected in numerous enforcement actions and

---

<sup>342</sup> *Id.*



investigations demonstrating that Walmart put profits and sales ahead of compliance, its customers and their communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

(1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

1164. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a “compliance program,” stated that it applied “all current and future Walmart Pharmacy locations.”

1165. The 2011 MOA specifically required that Walmart implement procedures to make certain that pharmacists identified red flags:

The program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice.

1166. During this period, Walmart required pharmacists to document a refusal to fill on a refusal-to-fill form. Walmart received these forms and so learned about problematic prescribing practices. Yet, Walmart did not use the information on them to alert its pharmacists about possible or known pill mill prescribers. Walmart did not even do so for nearby stores to which a customer was likely to take a refused prescription. It was particularly important for Walmart to do this because its pharmacists did not always work overlapping shifts and some “floated” between several stores, thereby reducing the pharmacists’ ability to communicate their concerns directly to one another.

1167. In fact, rather than use the information on the refusal-to-fill forms to fulfill its obligation to prevent diversion, Walmart instead used them solely to respond to complaints from patients or prescribers when a prescription was not filled.

1168. In the 2011 MOA, Walmart also promised to notify the DEA within seven days of a refusal to fill. When Walmart did so, it removed comments documenting the reasons for the refusal to fill, thereby denying the DEA access to information that Walmart's reporting was supposed to produce.

1169. Beginning in 2015, Walmart pharmacists documented their refusals to fill in a system known as Archer. Pharmacists could search Archer for refusals to fill for particular patients or prescribers, but the reasons for refusing to fill were still not provided. This limited pharmacists' ability to determine if a suspicious prescription was part of a pattern. Moreover, until February 2017, Walmart failed to inform its pharmacists that they could use Archer for this purpose.

1170. Although Walmart was supposed to revamp its dispensing compliance program, systemic failures continued. Walmart's corporate office not only failed to insist that Walmart implement adequate controls against diversion, it ignored concerns raised by Walmart pharmacists.

1171. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that "his leadership would not support his refusing to fill any 'legitimate' (written by a Dr) prescriptions and he stated that his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions[.]" When this pharmacist refused to fill a customer's controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist "sent a customer to a competitor," "expressed significant concern about how 'sending customers away' would impact the sales figures for the store," and insisted that "the store needs to fill every available prescription."

1172. Walmart filled prescriptions written by numerous known pill mill prescribers despite blatant red flags warranting investigations and refusals to fill. For example, between June 2013 and June 2014, Walmart filled over 700 prescriptions issued by W.W., a doctor in Fort Myers, Florida

whose medical license was revoked by the Tennessee Board of Medical Examiners for a failure to supervise nursing staff with “egregious prescribing habits” regarding controlled substances. Walmart did so despite red flags and direct warnings from Walmart pharmacists. These warnings included reports of multiple patients with prescriptions from W.W. arriving in the same vehicle and waiting in the parking lot for shipments of controlled substances to arrive at the pharmacy. Indeed, multiple pharmacists at multiple Walmart stores described W.W. on refusal-to-fill forms as running a “pill mill.” One of these even included specific details of W.W.’s practice indicative of pill mill operations such as accepting only cash, prescribing large quantities of oxycodone (and later hydrocodone), and dividing prescriptions in half to “give the appearance of smaller quantities being dispensed.” In December 2014 and January 2015, a pharmacy reported to Walmart’s compliance department that W.W.’s license had been suspended in two states. In spite of all of these red flags, Walmart continued to fill W.W.’s prescriptions.

1173. In October 2018, the DOJ had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. The investigation reportedly revealed that between 2011 and 2017, “Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse.”<sup>343</sup> They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington all “raised alarms to the company’s national compliance department about doctors.”<sup>344</sup> Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote: **“We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us.”**<sup>345</sup> Another described the same doctor as a “problem,” a “liability for us,” and a “risk that keeps [him] up at night,” cautioning “[t]his is a serious situation.”<sup>346</sup> Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that

---

<sup>343</sup> *Id.*

<sup>344</sup> *Id.*

<sup>345</sup> *Id.*

<sup>346</sup> *Id.*

a doctor was “under investigation by the DEA for what we believe is a pill mill operation” and that Rite Aid had begun to refuse to fill his prescriptions, prompting prescriptions from this prescriber, which were “almost solely narcotic and controlled prescriptions” to double.<sup>347</sup> Still, Walmart adhered to its policy of requiring a case-by-case analysis of each prescription from the suspected pill mill presented to any Walmart pharmacy; it would not block the prescriber in its system or allow a “blanket” refusal to fill. Walmart was more concerned with potential sales than it was with preventing diversion.

1174. Following its Texas settlement, Walmart claimed that the agreement only pertained to a handful of stores in that state and claimed that Walmart was “eager to comply with the law.”<sup>348</sup> A Walmart spokesperson further claimed, “We take record keeping seriously[,]” and “[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law.”<sup>349</sup>

1175. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and “taking action to fix its opioid dispensing practices.”<sup>350</sup> In fact, however, Walmart subsequently “acknowledged that it halted its cooperation in mid-2018.”<sup>351</sup>

1176. Federal prosecutors have also taken action against five Walmart and Sam’s Club Pharmacies in Texas, alleging that they failed to maintain records required by the CSA. Specifically, “accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA.”<sup>352</sup> A U.S. Attorney further explained that “[b]ecause of the pharmacies’ lack

<sup>347</sup> *Id.*

<sup>348</sup> Associated Press, *Wal-Mart Settles Drug Records Accusation* (Jan. 7, 2009), <http://prev.dailyherald.com/story?id=262762> (hereinafter, “*Wal-Mart Settles*”).

<sup>349</sup> *Id.*

<sup>350</sup> Fisinger & Bandler, *supra*.

<sup>351</sup> *Id.*

<sup>352</sup> *Wal-Mart Settles, supra*.

of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted.”<sup>353</sup>

1177. The enforcement actions against Walmart culminated in December 2020 when the DOJ filed an action for civil penalties, alleging:

As a nationwide dispenser *and* distributor of opioids, and given the sheer number of pharmacies it operates, Walmart was uniquely well positioned to prevent the illegal diversion of opioids. Yet, for years, as the prescription drug abuse epidemic ravaged the country, Walmart abdicated these responsibilities.

The DOJ identified numerous violations of Walmart’s obligations including failing to investigate orders that may be suspicious, shipping orders without conducting adequate investigations, designing SOM programs that did not capture all suspicious orders, continuing to fill prescriptions for known pill mill prescribers, and refusing to use its data and resource capabilities to identify problem prescribers, notify pharmacists of the identity of these prescribers, and institute programs to prevent filling their prescriptions.

1178. The federal MDL Court has denied a motion for summary judgment regarding the adequacy of Walmart’s suspicious order monitoring efforts.<sup>354</sup> In doing so, it “note[d] the record evidence suggests obvious deficiencies that a layperson could plainly recognize.”<sup>355</sup>

#### 4. Rite Aid

1179. Rite Aid distributed Schedule III (“CIIIs”) controlled substances (e.g., hydrocodone combination products) to its own Rite Aid stores until late 2014.

1180. According to ARCOS data, from 2006 until 2014, Rite Aid distributed over 126,484,750 dosage units of hydrocodone and/or oxycodone that were ultimately dispensed from its stores.

1181. Rite Aid’s controlled substance distribution process was fairly simple. Rite Aid used a computerized “auto-replenishment system” (“ARS”) through which individual Rite Aid pharmacies

<sup>353</sup> *Id.*

<sup>354</sup> See Opinion and Order Denying Walmart’s Motion for Summary Judgment, *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804 (N.D. Ohio Jan. 27, 2020), Doc. 3102.

<sup>355</sup> *Id.* at 4 n.12.

would generate orders that were sent to the distribution center (“DC”). This ARS relied directly on dispensing data and the dispensing patterns of individual Rite Aid stores. If the ARS generated an order that was above Rite Aid’s universal 5,000 dosage-unit (“DU”) threshold, the DC employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only “review” of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (i.e., that it was not a “fat-finger” error). If the pharmacy confirmed that the above-threshold order amount was correct or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped.

1182. Despite the extremely high threshold, Rite Aid had no procedure requiring anyone to report as suspicious orders over that threshold. Upon information and belief, even if a small number of “cut” orders were reported to the DEA, this reporting only happened after the orders had already been shipped.

1183. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. Yet Rite Aid did not use the Navicase/Naviscript system to identify—much less report—suspicious orders. Furthermore, assuming that the Navicase/Naviscript could identify suspicious orders, the Navicase/Naviscript data analysis only took place after shipment.

1184. The Rite Aid Asset Protection Department used “key performance indicators” (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft. Nevertheless, Rite Aid’s KPIs were not used to report suspicious orders.

1185. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions written by those prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate “suspicious prescriber” information that it may have collected when determining whether an order from any location was suspicious.

1186. Ultimately, Rite Aid’s distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. As a result of the company’s policies and procedures,

Rite Aid did not – and indeed, could not – identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order.

1187. Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees who were not able to actually do so.

1188. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In documenting such efforts, Rite Aid stated as follows:

The purpose of this project is to develop effective controls against the diversion of controlled substances and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

In the end, however, Rite Aid never adopted the new SOM system because it stopped distributing controlled substances before this system could be implemented.

1189. Rite Aid implemented a policy for dispensing “high-alert” controlled substances for the first time in 2013. The policy was a simple checklist consisting of six steps: 1) receive the prescription; 2) validate the prescription; 3) validate the prescriber; 4) validate the patient; 5) decide to dispense or not to dispense; and 6) report any suspicious activity. Yet Rite Aid provided little to no guidance on how to perform these vague tasks, rendering the policy little more than words on a page. In another example, Rite Aid only started to alert its pharmacists of patients’ attempts to get early refills – another red flag of diversion – in 2016.

1190. Rite Aid also did nothing to ensure that even its pro forma policies were followed. Rite Aid did not audit its pharmacies for compliance with either its own policies or the requirements of controlled substances laws.

1191. Rite Aid only started tracking “High Alert data” in September 2015 at the corporate level. Even then, it did not use the data to effectively comply with its obligation to prevent diversion

and ensure that only legal prescriptions were being filled at its pharmacies. For example, Rite Aid provided its pharmacists no visibility into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

1192. In contrast to its lack of robust policies to ensure only prescriptions issued for a legitimate medical purpose were dispensed, Rite Aid had numerous and detailed policies to ensure its profitability. The result of these policies was that Rite Aid pharmacists did not have the time, resources, or support to adequately discharge their legal duties as pharmacists or to enforce Rite Aid's limited anti-diversion policies.

1193. For example, in 2011, Rite Aid adopted a policy whereby it promised to fill prescriptions in 15 minutes or less.<sup>356</sup> If a prescription took more than 15 minutes to fill, the patient would get a \$5 gift card. Rite Aid touted the program as something consumers wanted, but many others recognized the danger of such a program. Numerous State Boards of Pharmacy objected. As the chair of the Illinois State Board of Pharmacy said, "This is 180 degrees away from everything we are trying to do in moving the pharmacy profession toward being patient information-focused rather than product-focused. And it's counter to our many efforts to improve patient safety."

1194. Despite eventually doing away with the 15-minute-or-less promise, Rite Aid continued to carefully track its pharmacists' prescription fill speeds, thereby ensuring that the pharmacists were unable to exercise their responsibilities to prevent diversion. In fact, Rite Aid pharmacies routinely filled prescriptions at a pace of multiple prescriptions per minute.

1195. Rite Aid's compensation policies also blocked pharmacists from preventing illegitimate prescriptions from being dispensed. Rite Aid's compensation policies provided bonuses that depended on the number of prescriptions—including opioids—dispensed. Even when Rite Aid eventually, ostensibly removed controlled substances from its bonus calculations, Rite Aid continued to evaluate its pharmacies on their profitability. Indeed, pharmacists' jobs depended on the

---

<sup>356</sup> Drug Topics, *Rite Aid offers 15-minute Rx guarantee*, May 15, 2011, <https://www.drugtopics.com/chains-business/rite-aid-offers-15-minute-rx-guarantee>.



profitability of the pharmacy; if the pharmacy was not profitable enough, staff would be laid off or the pharmacy closed entirely. A pharmacy's profitability is heavily dependent on its prescription volume, including those for controlled substances. So even if removed from bonus calculations, the amount of prescriptions dispensed by a pharmacy still acted as a powerful incentive for pharmacies to focus on dispensing all prescriptions, instead of only legal ones. Rite Aid did nothing to counter this perverse incentive and, in fact, encouraged profit over patient safety.

1196. The problem of illegal dispensing caused by Rite Aid's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Rite Aid's inadequate pharmacy staffing. Often, a single pharmacist staffed a location for an entire shift. This greatly undermined pharmacists' ability to evaluate each prescription carefully and in accordance with the law.

1197. Rite Aid also evaluated its pharmacies on customer service. Perversely though, Rite Aid considered a refusal to fill a prescription as a "service failure," despite pharmacists' legal obligation to refuse to fill certain prescriptions.

1198. Rite Aid helped to expand the market and increase the demand for prescription opioids by working in concert with manufacturers like Purdue. Capitalizing on Rite Aid's reach, Purdue worked with Rite Aid as early as 2001 to promote its highly addictive opioid, OxyContin.

1199. A central figure in this process was Dr. Allen Geiwitz, a medical liaison at Purdue from 1998 to 2004. In a presentation at the Rite Aid corporate office, Dr. Geiwitz successfully convinced Rite Aid management to assist Purdue in "proper pain management education," Purdue's euphemism for its misrepresentations concerning the addiction risk posed by OxyContin.

1200. The return on investment ("ROI") of such a program was clear to both Purdue and Rite Aid as shown in an internal email summarizing the presentation and its important consequences for expanding OxyContin sales and overcoming pharmacists' justifiable discomfort with dispensing large quantities of a dangerous and addictive drug:

To: Stup, Sharlene  
Cc: Geiwitz, Dr. Allen; Terifay, Terrence  
Subject: Rite Aid Program

Sharlene:

I wanted to follow up regarding today's pharmacy program with Dr. Al Geiwitz at the Rite-Aid Corporate Office. Dr. Al addressed in great detail an overview of pain management, the JCAHO pain standards, and most importantly the abuse and diversion issues. Dr. Al's discussion was well received and greatly appreciated by all in attendance, especially John Boyle, Regional Pharmacy Development Manager.

Our RO will best be defined by John, whose regional coverage extends to over 120 stores in Northeast Philadelphia, North Philadelphia, Mt. Airy, Bucks County, and other outreaches within our district. This is of great importance because prior to this program, John and many other pharmacists had concerns with regulatory issues surrounding purchasing quantities of OxyContin and identifying appropriate patients. Now, John has made himself available as an advocate and is willing to assist in our efforts in proper pain management education.

Sharlene, I am personally pleased with the efforts put forth by myself regarding this program. As you know, Rite-Aid has presented numerous challenges to the Philadelphia District in the past. I believe that by creating the need for proper education, I have the opportunity to make significant progress with the key Rite-Aid pharmacies in my territory.

Sincerely,  
Heather

1201. Both Purdue and Rite Aid recognized the importance of chain pharmacies and pharmacists in the effort to expand and sustain the demand for prescription opioids. In an email discussing the same presentation by Dr. Geiwitz, Ralph Lombardo, a Purdue sales manager, observed to Phil Cramer, Purdue's head of sales, that "pharmacists at the retail level" were the "most important audience... in highly sensitive areas" – presumably those already impacted, even in 2001, by the opioid epidemic.

1202. This email not only reveals Purdue's knowledge that its outreach and "education" efforts were successful, it also reveals Rite Aid's complicity as the company asked for at least two more presentations of the same misrepresentations concerning opioids:

.. Original Message ..

**From:** Lombardo, Ralph  
**Sent:** Wednesday, April 18, 2001 10:29 AM  
**To:** Cook, Dr. Mary; Gernitz, Dr. Allen; Corner, Phil  
**Cc:** Richards, Tim; Gasdia, Russell; DaBronzo, Dr. Joseph  
**Subject:** FW: Rate Aid Program

I want to thank Dr. Al Dr. Abby Crick, and Dr. Sabena for their support and efforts in the Philosophy area. This past fall, I taught and a student did a paper on me and Peterson through Socrates Stop performing as the Real Art GM asked who do they tell who do they tell for 25 more minutes and announced for me to come back in the year future to express the last of the presentations of a year until the return. Our class was all the time even they to put in the next semester and now especially in the many years to come.

7. 1963-1964

1244

1203. Although Rite Aid claims to be committed to working with “both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States,”<sup>35</sup> Rite Aid has failed in even its nominal efforts to prevent diversion.

1204. Confirming these systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions. As recently as January 2019, it paid \$177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

1205. In 2018, Rite Aid also agreed to pay a \$300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

1206. In 2017, Rite Aid paid \$834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least 1,298

<sup>57</sup> Rite Aid, Pharmacy, Health Information, <https://www.riteaid.com/pharmacy/health-information>.

times as a result of Rite Aid's failure to adequately maintain its internal database."<sup>358</sup> Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."<sup>359</sup>

1207. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and its regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.76(b).<sup>360</sup>

### VIII. ADDITIONAL ALLEGATIONS PERTAINING TO PUNITIVE DAMAGES

1208. Each Defendant knew that large and suspicious quantities of opioids were being poured into communities throughout the United States. Despite this knowledge, Defendants took either no steps or utterly inadequate steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed, as described above, Defendants acted in concert to maintain high quotas for their products and to ensure that suspicious orders would not be reported to regulators.

1209. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from federal and state governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately, and repeatedly threatened and accomplished harm to public health and safety and large-scale economic loss to hospitals, families, communities, and governments across the state.

---

<sup>358</sup> DEA, *Rite Aid Pays \$834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), <https://www.dea.gov/press-releases/2017-03-09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act>.

<sup>359</sup> *Id.*

<sup>360</sup> *Id.*

1210. As all of the governmental actions against Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and profits.

## **IX. COLLECTIVE CONDUCT ALLEGATIONS**

### **A. Conspiracy Allegations**

1211. On December 16, 2020, the Senate Finance Committee issued the findings in its most recent report, which were summarized as follows:

Our work reveals that opioid manufacturers have maintained extensive financial relationships with tax-exempt organizations, including pain advocacy groups, professional provider groups, and medical associations. In turn, these groups have sought to influence opioids prescribing practices and related Federal policy connected to opioid use and pain care that directly affects Medicare and Medicaid.<sup>361</sup>

1212. Between 1997 and 2012, Purdue, Endo, and J&J maintained strong financial ties to Front Groups and paid millions of dollars to them. They and others continued to make such payments through 2019, totaling another almost \$30 million during that period.

#### **1. Conspiracy Among the Marketing Defendants**

1213. The Marketing Defendants (including Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt) agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of chronic, non-cancer pain in order to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

1214. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing, such as KOLs, scientific literature, CMFs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and

---

<sup>361</sup> *December 2020 Senate Bipartisan Opioids Report, supra*, at 2.

intended to mislead consumers and medical providers, such as hospitals, about the risks, safety, and appropriate uses of opioids.

1215. The Marketing Defendants' collective scheme to increase opioid prescriptions, sales, revenues, and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

1216. The Marketing Defendants knew or had reason to know that none of these propositions are true.

1217. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers such as hospitals and healthcare payors about the risks, safety, and appropriate uses of opioids.

1218. What is particularly remarkable about the Marketing Defendants' effort is the seamless method by which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals, of the safety of opioids and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

1219. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful tool that achieved marketing goals that would have been impossible for a single or even a handful of the Marketing Defendants.

1220. For example, the Marketing Defendants pooled their vast resources and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants

1221. The most unnerving tactic utilized by the Marketing Defendants' network was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective, unbiased, and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

1222. The Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to the sheer number of publications, presentations, and CMEs the Marketing Defendants' resources enabled them to sponsor, they were able to create a false consensus about the safety and efficacy of opioids for chronic pain.

1223. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. Although, as discussed above, the letter does not address patients given long-term opioid prescriptions or provided opioids to administer to themselves at home nor how frequently or infrequently and in what doses the narcotics were administered, the Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk posed by opioids. The Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

1224. The Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers such as hospitals that opioids were not a concern. The enormous impact of the Marketing Defendants' misleading amplification of this

letter was well documented in another *NEJM* letter, discussed above, describing the way the one-paragraph 1980-letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

## **2. Conspiracy Among the Marketing Defendants and the Supply Chain Defendants**

1225. In addition, and on an even broader level, all the Marketing Defendants (including Purdue, the Sacklers, the Purdue Officer Defendants, and Mallinckrodt) and the Supply Chain Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. The Marketing and Supply Chain Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. The Marketing and Supply Chain Defendants did so to increase sales, revenue, and profit from their opioid products.

1226. The interaction and length of the relationships between and among the Marketing and Supply Chain Defendants reflects a deep level of interaction and cooperation. The Marketing and Supply Chain Defendants operated together as a united entity on multiple fronts to engage in the unlawful sale of prescription opioids.

1227. The Marketing and Supply Chain Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the numerous ways set forth above, including, for example, membership in HDA.

1228. The Marketing and Supply Chain Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties to report suspicious orders. The Marketing and Supply Chain Defendants overwhelmingly agreed on the same approach – to fail to identify, report, or halt suspicious opioid orders and to prevent diversion. The Marketing and Supply Chain Defendants’ agreement to restrict reporting provided an added layer of insulation from scrutiny for the entire industry as the Marketing and Supply Chain Defendants were



collectively responsible for each other's compliance with their reporting obligations. The Marketing and Supply Chain Defendants were aware, both individually and collectively, of the suspicious orders that flowed directly from the Marketing and Supply Chain Defendants' facilities to pharmacies and ultimately into the community.

1229. The Marketing and Supply Chain Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the government's attention. As a result, the Marketing and Supply Chain Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with the authorities.

1230. The desired consistency and collective end goal were achieved. The Marketing Defendants and Supply Chain Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

#### **B. Joint Enterprise Allegations**

1231. Defendants entered into an agreement with respect to opioids and/or distribution of opioids throughout the United States, including in New York and Plaintiffs' communities.

1232. The agreement had a common purpose: to promote the sale and distribution of opioids through the marketing, distribution, and/or dispensing of opioids throughout the United States, including in New York and Plaintiffs' communities, in violation of New York's pharmaceutical laws and regulations and the common law of fraud and nuisance.

1233. Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids throughout the United States, including in New York.

1234. Defendants had an equal right to a voice in the direction of the enterprise.

### **X. TOLLING AND FRAUDULENT CONCEALMENT**

1235. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material facts and knowledge from Plaintiffs and others to induce them to purchase and administer opioids as set forth in detail above.

1236. Defendants invented the term “pseudoaddiction” and promoted it to the medical community, including Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. The Marketing Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

1237. By overstating the benefits of and evidence for the use of opioids to treat chronic pain and understating their very serious risks, including addiction and death; by falsely promoting abuse-deterrent formulations as a solution to abuse; by falsely claiming that OxyContin provides 12 hours of relief; by falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and by doing all of this while knowing full well that their statements were misrepresentations of material facts, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact, as detailed herein.

1238. Defendants intended and knew that Plaintiffs would rely on their misrepresentations, omissions, and concealment and that such reliance would cause harm to Plaintiffs. The medical community, including Plaintiffs, were duped by Defendants’ campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing.

1239. Plaintiffs reasonably relied on Defendants’ misrepresentations and omissions in writing and filling prescriptions for Defendants’ opioids. The use of Defendants’ opioid medicines became widespread and continuous as a result.

1240. The continued tortious and unlawful conduct by the Defendants has caused a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants’ wrongdoing and unlawful activity have not ceased. The nuisance they created remains unabated.

1241. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed their wrongful acts and the material information pertinent to their discovery. As a result of Defendants' conduct, Plaintiffs did not know, and could not have known through the exercise of reasonable diligence, of their claims.

1242. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result, Plaintiffs were unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

## **XI. CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF**

#### **New York Consumer Protection from Deceptive Acts and Practices Statute, General**

#### **Business Code §§ 349, *et seq.***

#### **(Against the Marketing Defendants and the National Retail Pharmacies)**

1243. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1242 of this Complaint, as if fully set forth herein.

1244. This claim is brought under Article 22-A of the General Business Code.

1245. This article makes it unlawful to engage in "acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state, N.Y. Gen. Bus. Law § 349" or to engage in "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state," *id.* § 350.

#### **A. Defendants engaged in deceptive consumer-oriented practices.**

1246. Members of the public who are or might be prescribed opioids are consumers, so deceptive practices directed to them are consumer-oriented. These practices include direct-to-consumer branded and unbranded advertising and the dispensing of opioids to consumers in

circumstances suggesting that those opioids were being abused or misused or that they were not prescribed for a legitimate medical purpose.

1247. In addition, practices directed to encourage greater prescription and administration of opioids also directly affected individual patients as consumers because they ultimately consume and pay for products that they would not have had to consume and pay for had Defendants not promoted excessive opioid prescription and use. These practices included in-person detailing of prescribers, publications and advertisements in scientific journals read by doctors and other hospital employees, modifications to the standards of the Joint Commission that controls hospital accreditation, CMEs and other presentations to doctors and other hospital employees, and the creation and dissemination of pro-opioid treatment guidelines, among other things.

**B. Defendants' trade practices were misleading in a material way.**

1248. The Marketing Defendants misrepresented the characteristics, uses, and benefits of opioids by misrepresenting the relative safety of opioids, their appropriateness for treatment of chronic pain, the risk of addiction, the false concept of "pseudoaddiction," and the evidentiary value of the Porter & Jick letter.

1249. The Marketing Defendants misrepresented the sponsorship, approval, or certification of the prescription opioids they sold. They did so by encouraging off-label use of opioids for the treatment of conditions for which the drugs were not approved but without making it clear that these uses were unapproved. They also did so by using ostensibly neutral Front Groups and KOIs as proponents of extensive use of opioid therapy for patients with chronic pain. Because the Front Groups had names suggestive of a neutral and patient-centric focus but were, in relatively, the Marketing Defendants' funded mouthpieces, the Marketing Defendants' use of these groups misrepresented the extent to which prescription opioids were approved and endorsed by independent groups.

1250. The Marketing Defendants disparaged non-opioid treatments for chronic pain through misleading overstatements of the risks and maximum dose of those treatments.

1251. Because Defendants knew that patients reasonably rely on the expertise of health care providers to determine whether a particular prescription drug is safe, effective, and appropriate, Defendants were able to use their representations to the medical community and consumers directly to take advantage of consumers' ignorance. Once these patients developed a physical tolerance to the opioids they had been prescribed, they had a physical infirmity that prevented them from taking action to stop their use of opioids.

1252. The Marketing Defendants engaged in unconscionable, false, or deceptive acts or practices in business, commerce, or trade.

1253. By misrepresenting the benefits and risks of opioids, the Marketing Defendants employed deception, fraud, or false pretense in connection with the sale or advertisement of goods.

1254. By concealing and suppressing information about the risks of opioids while intending that patients, prescribers, and hospitals would rely on that information to prescribe, administer, and consume prescription opioids, the Marketing Defendants violated sections 349 and 350 of the General Business Code.

1255. The National Retail Pharmacies engaged in the deceptive trade practice of filling prescriptions that displayed red flags indicative of abuse and diversion, including those written by "pill mill" prescribers, or that were otherwise medically inappropriate. Dispensing dangerous drugs such as opioids under circumstances in which they are not needed or will cause harm to the pharmacies' customers, their families, and their communities without fully disclosing these facts is deceptive.

1256. The false representations, misrepresentations, and omissions were material because the information misrepresented or concealed involved the relative efficacy and safety of prescription opioids. That information would reasonably influence the decisions of hospitals, prescribers, and patients with regard to beginning or continuing opioid therapy.

**C. Defendants' deceptive practices injured Plaintiffs.**

1257. Defendants' deceptive trade practices caused the direct and foreseeable losses alleged in this Complaint, including the cost of purchasing prescriptions opioids Plaintiffs would not

otherwise have purchased were it not for the increased patient demand for opioids generated by Defendants' deceptive trade practices and the financial impact of unreimbursed and more expensive care necessitated by patients' opioid-related conditions, which would not have occurred had Defendants not engaged in deceptive trade practices that drove increasing opioid use and misuse.

1258. The Marketing Defendants and the National Retail Pharmacies are liable to Plaintiffs for the actual damages they sustained.

1259. Plaintiffs seek to recover the damages they suffered as a result of Defendants' deceptive statements and representations along with costs and reasonable attorneys' fees.

1260. Under New York law, the Marketing Defendants and the National Retail Pharmacies are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

## **SECOND CLAIM FOR RELIEF**

### **Negligence**

#### **(Against All Defendants)**

1261. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1260 of this Complaint, as if fully set forth herein.

1262. This claim is brought under the common law of negligence.

#### **A. Defendants Owed a Duty of Care**

1263. Defendants had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs. Defendants knew or should have known that opioids were likely to cause addiction. Defendants owed their aforesaid duties to Plaintiffs because the injuries alleged herein were foreseeable by Defendants.

1264. A reasonable person could foresee the probability of occurrence of injury to Plaintiffs. Reasonably prudent wholesale drug manufactures, marketers, distributors, and dispensers of opioids would have anticipated the scourge of opioid addiction, especially when being warned and prosecuted by law enforcement repeatedly. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of highly dangerous opioids.

**B. Defendants Breached Their Duty Of Reasonable Care**

1265. Each Defendant breached its aforesaid duties of care.

**1. Negligent Marketing (Marketing Defendants, Sales Representative Defendants, and CVS)**

1266. The Marketing Defendants, the Sales Representative Defendants, and CVS marketed opioids in a negligent and improper manner by:

- a. Overstating the benefits of chronic opioid therapy by promising improvement in patients' function and quality of life and by failing to disclose the lack of evidence supporting long-term use;
- b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;
- c. Overstating opioids' superiority compared with other treatments, such as non-opioid analgesics, physical therapy, and other alternatives;
- d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; and
- e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

1267. It was marketing by the Marketing Defendants, the Sales Representative Defendants, and CVS – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

1268. The Marketing Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent. Through unbranded materials outside of FDA oversight, the Marketing Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on the Marketing Defendants' branded marketing materials and drug labels.

1269. The Marketing Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations; and (g) detailing of prescribers by sales representatives, including the Sales Representative Defendants.

**2. Negligent Distribution (Marketing and Supply Chain Defendants) and Negligent Dispensing (National Retail Pharmacies)**

1270. The Marketing and Supply Chain Defendants distributed opioids in an improper manner (as described in more detail in Section VII) by:

- a. Distributing, selling, and/or dispensing opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing, selling, and/or dispensing opioids without maintaining effective controls against diversion;
- c. Choosing not to or failing to effectively monitor for suspicious orders;
- d. Choosing not to or failing to report suspicious orders;
- e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and
- f. Distributing, selling, and/or dispensing opioids prescribed by “pill mills” when Marketing and Supply Chain Defendants knew or should have known the opioids were being prescribed by “pill mills.”

1271. One set of relevant standards of care is provided in the various federal and state laws regulating dangerous drugs. Among other things, these laws and regulations require

- a. That manufacturers and distributors maintain effective control against diversion of controlled substances, N.Y. Pub. Health Law §§ 3312(1)(c), 3316(1)(a);
- b. That manufacturers and distributors comply with all applicable state and federal laws and regulations relating to the manufacture or distribution of controlled substances, including the federal Controlled Substances Act and its implementing regulations, N.Y. Pub. Health Law §§ 3312(1)(d), 3316(1)(b);



- c. That manufacturers and distributors establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and others of unusual frequency, N.Y. Comp. Codes R. & Regs. tit. 10, § 80.22;
- d. That pharmacies only dispense controlled substances in good faith and in the usual course of professional practice, N.Y. Pub. Health Law § 3331(2);
- e. That pharmacies only dispense controlled substances for legitimate medical purposes only, N.Y. Comp. Codes R. & Regs. tit. 10, §§ 80.65, 910.2(f);
- f. That pharmacies may not knowingly fill a prescription issued to an addict or habitual user of controlled substances that is not issued in the course of professional treatment but instead to provide the addict or user with the substances, N.Y. Comp. Codes R. & Regs. tit. 10, § 80.65;
- g. That manufacturers, distributors, and pharmacies must notify the state of each incident or alleged incidence of possible diversion of control substances, including diversion or suspected diversion by end consumers, N.Y. Comp. Codes R. & Regs. tit. 10, § 80.110(a).

1272. The duties imposed by statute or regulation on pharmacists extend to the owners of pharmacies. N.Y. Educ. Law § 6808(e).

1273. In the instant case, as detailed above, the New York State Controlled Substances Act, N.Y. Pub. Health Law §§ 3300, *et seq.*, the Education Law provisions regulating the profession of pharmacy, N.Y. Educ. Law §§ 6800, *et seq.*, and their implementing regulations require that Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

1274. Defendants have violated New York law by failing to report suspicious orders of opioid pain medications, by failing to maintain effective controls and procedures against diversion of opioids into other than legitimate medical channels, and by failing to operate a system to stop or at least to diligently respond to the order which were flagged or should have been flagged as suspicious.

1275. Defendants have willfully turned a blind eye to the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

1276. The National Retail Pharmacies negligently acted with others by dispensing controlled substances that they knew or should have known were for illegitimate medical purposes, including by filling prescriptions written by physicians operating pill mills. This conduct created and continued addictions to prescription medications in this state.

1277. Defendants' violations constitute negligence and negligence per se.

1278. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

1279. By their acts and omissions, Defendants have proximately caused and substantially contributed to Plaintiffs' damages by violating New York law, by creating conditions which contribute to the violations of New York laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

1280. Plaintiffs have suffered and will continue to suffer enormous damages as the proximate result of Defendants' failure to comply with New York law.

1281. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

1282. Plaintiffs are within the class of persons that the New York State Controlled Substances Act, N.Y. Pub. Health Law §§ 3300, *et seq.*, the Education Law provisions regulating the profession of pharmacy, N.Y. Educ. Law §§ 6800, *et seq.*, and their implementing regulations were intended to protect.

1283. The harm that has occurred is the type of harm that the New York State Controlled Substances Act, N.Y. Pub. Health Law §§ 3300, *et seq.*, the Education Law provisions regulating the

profession of pharmacy, N.Y. Educ. Law §§ 6800, *et seq.*, and their implementing regulations were intended to guard against.

1284. Defendants' willful and/or grossly negligent failure to comply with federal and state laws regulating the profession of pharmacy and controlled substances constitutes "unprofessional conduct," which is itself a violation of New York law.

1285. Defendants breached their duty by failing to take reasonable steps to prevent or reduce the unlawful and/or inappropriate distribution of the opioids.

1286. As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered and continue to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids.

**C. Defendants' Breaches of Care Were Intentional, Willful, Wanton, Reckless, and/or Grossly Negligent.**

1287. Defendants' breaches of care were intentional, willful, wanton, reckless, and/or grossly negligent. Defendants purposely overstated the benefits of chronic opioid therapy and opioids' superiority compared with other treatments; actively and continuously promoted the use of opioids for improvement in patients' function and quality of life but failed to disclose the lack of evidence supporting their long-term use; mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; intentionally trivialized or obscured opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death; continuously marketed opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

1288. Defendants have willfully turned a blind eye to the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base substantially comprised of individuals who are abusing and/or diverting prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

1289. The National Retail Pharmacies have willfully blinded themselves to the actual facts by regularly dispensing large quantities of controlled substances under circumstances that violate their

statutory and common law duties to prevent diversion and ensure that these drugs are dispensed appropriately.

1290. Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably or probably result in injury to others, specifically hospitals such as Plaintiffs, which would be subjected to increased costs of providing healthcare treatment to patients with opioid conditions (for which they would have a lower rate of realization) as well as other costs associated with diagnosis, treatment of opioid-related conditions, and operation of its business in the midst of an opioid epidemic.

#### **D. Causation and Damages**

1291. As a proximate result of Defendants' conduct, Defendants have caused Plaintiffs' injury related to the diagnosis and treatment of opioid-related conditions. Plaintiffs have suffered a massive financial impact as a result of the increased cost of providing health care to patients with opioid-related conditions and elevated operational expenses incurred to respond to the conditions created by the opioid epidemic.

1292. The injuries to Plaintiffs would not have happened in the ordinary course of events had Defendants exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the manufacture, marketing, sale, and distribution of opioids.

1293. Plaintiffs are entitled to recover compensatory damages as a result of Defendants' negligence, in an amount to be determined at trial.

1294. As a result of Defendants' intentional, willful, wanton, and/or reckless conduct described herein, Plaintiffs are entitled to treble, punitive, exemplary, and/or otherwise enhanced damages to the full extent available under New York law, in an amount to be determined at trial.

1295. Under New York law, Defendants are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

1296. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief. Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

### **THIRD CLAIM FOR RELIEF**

#### **Nuisance**

#### **(Against All Defendants)**

1297. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1296 of this Complaint, as if fully set forth herein.

1298. This claim is brought under the common law of nuisance.

1299. This claim is brought against all Defendants as principles and as co-conspirators with each other and with others not charged in this Complaint.

1300. All Defendants substantially participated in nuisance-causing activities.

1301. The Marketing Defendants, the Sales Representative Defendants, and CVS participated in nuisance-causing activities through, as described in Sections V and VI, their marketing of opioids.

1302. The Marketing and Supply Chain Defendants participated in nuisance-causing activities by distributing, selling, and/or dispensing opioids, as described in Section VII, and/or by otherwise exacerbating the flood of opioids into Plaintiffs' communities in ways that unreasonably interfere with, endanger or injure the public health, welfare, and safety in Plaintiffs' communities.

1303. The nuisance created by Defendants is the over-saturation of opioids distributed and dispensed for illegitimate purposes among Plaintiffs' patient population and in the geographic areas served by Plaintiffs as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

1304. Defendants, individually and acting through their employees and agents, through fraudulent and deceptive marketing and other fraudulent schemes as described herein, created and

maintained the opioid epidemic in Plaintiffs' communities. This epidemic is harmful and disruptive to and substantially and unreasonable annoys, injuriously affects, endangers, and interferes with the safety, health, morals, comfort, and general welfare of the public.

1305. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs as well as to unintended users, including criminals, children, and people at risk of overdose or suicide.

1306. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion, and misuse of controlled substances and failing to adequately design and operate systems to detect, halt, and report suspicious orders of controlled substances.

1307. Defendants' activities unreasonably interfere with Plaintiffs' economic rights and the reasonable use of Plaintiffs' property. Plaintiffs' resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating or reducing available resources that could be used to benefit the community within the geographic areas served by Plaintiffs.

1308. Defendants' interference with Plaintiffs' rights are unreasonable because that interference:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;
- b. Has harmed and will continue to harm the communities and neighborhoods that Plaintiffs serve;
- c. Is proscribed by statutes and regulations, including those applicable to controlled substances;
- d. Is of a continuing nature and has produced long-lasting effects;
- e. Is known or reasonably should be known by Defendants to have a significant effect upon Plaintiffs; and
- f. Has inflicted substantial costs on Plaintiffs.

1309. New York specifically provides that the maintenance of any "premises, place or resort where persons come or gather for purposes of engaged in the unlawful sale of controlled substances"

constitutes criminal nuisance. N.Y. Penal Law § 240.46. Defendants' facilities within New York from which they sold prescription opioids in contravention of the laws and regulations governing sale of controlled substances are thus public nuisances.

1310. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

1311. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction or misuse, in failing to identify, halt, and report suspicious opioid transactions, or in filling prescriptions not written for legitimate medical purposes.

1312. Defendants knew of the public health hazard their conduct would create. It was foreseeable to Defendants that their conduct would unreasonably interfere with the ordinary comfort, use, and enjoyment of residents in the communities in which Plaintiffs operate and throughout the State of New York.

1313. Defendants' conduct is unreasonable, intentional, unlawful, reckless, and/or negligent.

1314. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. The Supply Chain Defendants had the power to shut off the supply of illicit opioids in the geographic areas served by Plaintiffs.

1315. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity. In short, the Defendants created a mess, leaving to the Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

1316. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the public at large, by individual users, and by governmental entities. Plaintiffs

have suffered a massive financial impact as a result of the increased cost of providing health care to patients with opioid-related conditions and elevated operational expenses incurred to respond to the conditions created by the opioid epidemic.

1317. The public nuisance, i.e., the opioid epidemic, created, perpetuated, and maintained by Defendants can be abated, and further recurrence of such harm and inconvenience can be abated.

1318. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

1319. Under New York law, Defendants are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

1320. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief. Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

1321. Therefore, Plaintiffs demand judgment in their favor against Defendants for injunctive relief, abatement of the public nuisance, and damages in an amount to be determined, together with all costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

#### **FOURTH CLAIM FOR RELIEF**

##### **Unjust Enrichment**

##### **(Against All Defendants)**

1322. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1321 of this Complaint, as if fully set forth herein.

1323. This claim is brought under the New York common law of unjust enrichment.

1324. Plaintiffs provided unreimbursed healthcare treatment and healthcare treatment at increased cost to patients with opioid-related conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of



treating these patients' opioid conditions. This is because Defendants derived their profits from causing the patients' opioid conditions.

1325. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause (and in fact have caused) hospitals throughout the United States to provide unreimbursed healthcare treatment and healthcare treatment at increased cost to patients with opioid-related conditions that Defendants were responsible for creating.

1326. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

1327. Plaintiffs purchased and continue to purchase opioid products marketed and sold by Defendants. Defendants directly marketed their opioid products through false, deceptive, and unfair marketing of opioid products purchased by Plaintiffs, its pharmacy representatives, and its doctors.

1328. Defendants have received and continue to receive the benefit of the false, deceptive, and unfair marketing and sales of their opioid products directly to Plaintiffs, their pharmacy representatives, and their doctors.

1329. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it against equity and good conscience for Defendants to retain the benefit without payment of its value.

1330. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

1331. Defendants have therefore been unjustly enriched at the expense of Plaintiffs.

1332. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiffs.

1333. Because Defendants' unjust enrichment resulted from their coordinated conduct, they are jointly and severally liable to Plaintiffs.

**FIFTH CLAIM FOR RELIEF**

**Fraud and Deceit**

**(Against All Defendants)**

1334. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1333 of this Complaint, as if fully set forth herein.

1335. The Count is brought against all Defendants, as principals and as co-conspirators with each other.

1336. Defendants made false representations and otherwise failed to disclose material facts to physicians and consumers throughout New York and the United States.

1337. Defendants made such false representations for the purposes of inducing the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

1338. Defendants had knowledge of the falsity and materiality of the representations, or made the representations in reckless disregard of whether the representations were true or false, and had knowledge of the materiality of the facts they were intentionally or recklessly concealing.

1339. Specifically, the Marketing Defendants' and the Sales Representative Defendants' knowing false representations and deceptions as to material facts during the relevant period, which were intended to induce reliance, include but are not limited to:

- a. Misrepresentations overstating the benefits of and evidence supporting the use of opioids in chronic pain;
- b. Misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;
- c. Misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;
- d. Misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;
- e. Misrepresentations that screening tools effectively prevent addiction;

- f. Misrepresentations concerning the comparative risks of NSAIDs and opioids;
- g. Misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;
- h. Misrepresentations that evidence supports the long-term use of opioids for chronic pain;
- i. Misrepresentations that chronic opioid therapy would improve patients' function and quality of life;
- j. False portrayals of their efforts and/or commitment to rein in the diversion and abuse of opioids;
- k. Misrepresentations that withdrawal is easily managed;
- l. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;
- m. Purdue's misrepresentations that OxyContin provides a full twelve hours of pain relief;
- n. Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;
- o. Mallinckrodt's misrepresentations that it meets or exceeds legal requirements for controlling against diversion of controlled substances it has been entrusted to handle;
- p. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;
- q. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of non-cancer pain;
- r. Purdue and Practice Fusion's collaborative work to develop clinical decision alerts in Practice Fusion's electronic health records system that encouraged healthcare professionals using the platform to increase prescriptions of Purdue's opioid products;
- s. The Marketing Defendants' use of Front Groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;
- t. The Marketing Defendants' creation of a body of deceptive, misleading, and unsupported medical and popular literature, advertisements, training materials, and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) were thus more likely to be relied upon by physicians, patients, and payors; and,

- u. Such other misrepresentations and deceptions outlined above.

1340. By engaging in the acts and practices alleged herein, the Marketing Defendants and the Sales Representative Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that the Marketing Defendants and the Sales Representative Defendants had a duty to disclose by virtue of their other representations, including but not limited to:

- a. Opioids are highly addictive and may result in overdose or death;
- b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;
- c. High dose opioids subject the user to greater risks of addiction, other injury, and/or death;
- d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, NAS, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;
- e. Claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;
- f. Purdue's 12-hour OxyContin fails to provide a full twelve hours of pain relief in many patients;
- g. Purdue and Endo's abuse-deterrent formulations are not designed to address and have no effect on the most common route of abuse (oral), can be defeated with relative ease, and may increase overall abuse;
- h. The Marketing Defendants' failure to report suspicious prescribers and/or orders;
- i. Cephalon's failure to disclose that Actiq and Fentora were not approved for non-cancer pain;
- j. Practice Fusion's failure to provide, in its Pain Clinical Decision Support Alerts, clinical guidelines from the CDC or NIAJN for prescribing opioids for chronic pain;
- k. The Marketing Defendants' failure to disclose their financial ties to and role in connection with KOLs, Front Groups, and deceptive literature and materials, as more fully described above; and

- I. Such other omissions and concealments as described above in this Complaint.

1341. In each of the circumstances described in the foregoing paragraph, the Marketing Defendants and the Sales Representative Defendants knew that their failure to disclose rendered their representations untrue or misleading.

1342. In addition, and independently, the Marketing Defendants and the Sales Representative Defendants had a duty not to deceive Plaintiffs, their agents, their communities, physicians, and the public because Defendants had in their possession unique material knowledge, which was unknown and unknowable.

1343. The Marketing Defendants and the Sales Representative Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

1344. The Marketing Defendants and the Sales Representative Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; these Defendants intended and knew that this reasonable and rightful reliance would be induced their misrepresentations and omissions; and, these Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

1345. The Marketing Defendants and the Sales Representative Defendants were not alone in this, the Supply Chain Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. These deceptions include but are not limited to:

- a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at the center of a sophisticated supply chain and, therefore, are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers;

- b. Acknowledgment of the Distributor Defendants that because of their unique position within the “closed” system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;
- c. Cardinal Health claiming to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse;”
- d. AmerisourceBergen taking the same position as its counterparts within the industry and stating that it was “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances;”
- e. Misrepresenting that they were in compliance with their statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs and with their obligation to undertake such efforts as responsible members of society; and
- f. Such other omissions or concealments as described above in this Complaint.

1346. By engaging in the acts and practices alleged herein, the Supply Chain Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that the Supply Chain Defendants had a duty to disclose by virtue of their other representations, including but not limited to:

- a. That there was no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiffs’ communities;
- b. That they filled prescriptions for which there was no legitimate medical purpose;
- c. That they failed to report suspicious orders;
- d. That they failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain customers;
- e. That they failed to prevent diversion from legitimate to non-legitimate channels;
- f. That they failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;

g. That they failed to keep and maintain accurate records of Schedule II – V controlled substances; and

h. Such other omissions or concealments as alleged above in this Complaint.

1347. The Supply Chain Defendants intended and had reason to expect under the operative circumstances that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein and that Plaintiffs would act or fail to act in reasonable reliance thereon.

1348. The Supply Chain Defendants intended that Plaintiffs, their agents, their communities, physicians, and persons on whom Plaintiffs and their agents relied would rely on these Defendants' misrepresentations and omissions; Defendants intended and knew that this reasonable and rightful reliance would be induced by these Defendants' misrepresentations and omissions; and Defendants intended and knew that such reliance would cause Plaintiffs to suffer loss.

1349. Plaintiffs rightfully, reasonably, and justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. As Defendants knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance. Plaintiffs' injuries were directly and proximately caused by this reliance.

1350. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiffs from making a more timely and effective response to the opioid epidemic.

1351. Defendants' false representations and omissions were material and were made and omitted intentionally and recklessly.

1352. Defendants' misconduct alleged in this case is ongoing and persistent.

1353. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

1354. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons and said actions had a great probability of causing substantial harm.

1355. Under New York law, Defendants are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

1356. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief. Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

1357. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants as well as attorney fees and costs, and pre- and post-judgment interest.

#### **SIXTH CLAIM FOR RELIEF**

##### **Fraudulent Concealment**

##### **(Against All Defendants)**

1358. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1357 of this Complaint, as if fully set forth herein.

1359. The Count is brought against all Defendants, as principals and as co-conspirators with each other and with others who are not named in this Complaint.

1360. Defendants failed to disclose material facts, where a legal or equitable duty existed, with the intent that others act or refrain from acting in reliance on the non-disclosure, and which non-disclosure was in fact relied upon.

1361. The material facts that Defendants failed to disclose are set forth in Claim Five (Fraud and Deceit) and throughout this Complaint and are incorporated by reference.



1362. Defendants had a duty to disclose these facts, arising from obligations under federal and state controlled substance laws, as well as duties under common law, as described in the Second Claim for Relief (Negligence) to avoid endangering the community by flooding it with opioids and creating an epidemic.

1363. Moreover, Defendants in many instances had unique, material knowledge as to the effects of opioids, the falsity of their claims concerning the efficacy of their use, and the magnitude of their distribution. This sort of information was generally unknown or unknowable, and if disclosed in any meaningful way would have prompted increased regulatory or government scrutiny of the opioid industry, threatening Defendants' profits.

1364. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants' concealment of material fact.

1365. Under New York law, Defendants are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

1366. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief. Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

1367. Plaintiffs therefore demand judgment in their favor against Defendants for compensatory, exemplary, and punitive damages in an amount to be determined by a jury, together with all the costs of this action, including prejudgment interest, post-judgment interest, costs and expenses, attorney fees, and such other relief as this Court deems just and equitable.

**SEVENTH CLAIM FOR RELIEF**

**Civil Conspiracy**

**(Against All Defendants)**

1368. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1367 of this Complaint, as if fully set forth herein, including, but not limited to, the Collective Conduct Allegations of Section IX.

1369. Plaintiffs bring this claim under the common law providing for the civil liability of persons who conspire to commit one or more unlawful or tortious acts including nuisance, fraud, and fraudulent concealment.

1370. At least one of the Defendants and unnamed co-conspirators committed an intentional tort in furtherance of the conspiracy.

1371. All named Defendants conspired with each other and with various entities and persons who are not named in this Complaint to commit the acts upon which Claims One through Six are based. At the core of the conspiracy was an agreement to do unlawful acts or to do lawful acts by unlawful means. The goals of the conspiracy, that is, the gist of the conspiratorial agreement, was to expand the market for opioids, and to accomplish this, Defendants falsely marketed opioids and failed to control against diversion in the face of overwhelming evidence that diversion was taking place.

1372. Even if some of the Distributor Defendants were competitors with each other in some spheres of business, or some of the Marketing Defendants were competitors with each other, or some of the Retail Chain Pharmacies were competitors with each other, it served all of their interests to promote opioid use, to sell as many opioids as possible, to create a marketplace where massive distribution and use of and addiction to opioids was the norm, and to look the other way and fail to report or control massive drug diversions against overwhelming evidence of the epidemic they were creating. They acted in concert and in tacit and explicit agreement to pursue these goals.

1373. Each Defendant is liable for its co-conspirators' acts in furtherance of the conspiracy.

1374. Each of the Claims for Relief asserted in this Complaint arises from acts in furtherance of the conspiracy described in this Complaint and in this Count, and each Defendant is liable for the conduct of its co-conspirators in the commission of those torts and/or statutory violations.

1375. Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against its commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities when under a legal duty to do. Each Defendant acted against its commercial interests in this regard due to an actual or tacit agreement between Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

1376. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiffs.

1377. Defendants' conspiracy and their actions and omissions in furtherance thereof caused the direct and foreseeable losses alleged herein.

1378. Defendants' misconduct alleged in this case is ongoing and persistent.

1379. Because of Defendants' dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with laws concerning the distribution of opioids, Defendants are responsible for the costs.

1380. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

1381. Under New York law, Defendants are jointly and severally liable to Plaintiffs because Plaintiffs seek only economic damages.

1382. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief.

Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

1383. Plaintiffs therefore request that this Court enter an order awarding judgment in its favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

**EIGHTH CLAIM FOR RELIEF**

**Concert of Action**

**(Against All Defendants)**

1384. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 1383 of this Complaint, as if fully set forth herein, including, but not limited to, the Collective Conduct Allegations of Section IX.

1385. Plaintiffs bring this claim under the New York common law tort of concert of action.

1386. Defendants, along with other persons not named in this Complaint (including Purdue, the Purdue Officers, Sackler, and Mallinckrodt), committed the tortious conduct that forms the basis of Claims One through Six while acting in concert with one another pursuant to a common design.

1387. Each Defendant engaged in at least one tortious act of fraud, fraudulent concealment, or creation of a public nuisance.

1388. At least one Defendant committed its tortious act in furtherance of the joint goal of all Defendants to flood New York and communities served by Plaintiffs

1389. The tortious conduct in which Defendants and others engaged was inherently dangerous or posed a substantial risk of serious harm. The fact that prescription opioid manufacture, distribution, and dispensing is so heavily regulated demonstrates the severity of harm attendant upon negligent or intentional tortious misconduct in this area.

1390. The nature of the agreement between Defendants is set forth in Claim Seven (Civil Conspiracy) and throughout this Complaint; these allegations are incorporated by reference.

1391. Defendants' concert of action and their actions and omissions in furtherance thereof

caused the direct and foreseeable losses alleged herein.

1392. Defendants' misconduct alleged in this case is ongoing and persistent.

1393. Under New York law, Defendants are jointly and several liable to Plaintiffs because Plaintiffs seek only economic damages.

1394. Defendants acted in concert with one another and with Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt to commit the intentional torts alleged in this Claim for Relief. Therefore, each Defendant is jointly and severally liable for the portions of fault attributable to each of the other Defendants and to Purdue, the Sacklers, the Purdue Officers, and Mallinckrodt.

1395. Plaintiffs therefore request that this Court enter an order awarding judgment in its favor against Defendants, compelling Defendants to pay the direct and consequential damages, and awarding Plaintiffs such other, further, and different relief as this Court may deem just and proper.

## **XII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs ask that the Court:

- A. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiffs;
- B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages; treble damages; punitive damages; pre-judgment and post-judgment interest as provided by law and at the highest legal rate;
- C. Award such equitable relief against Defendants as the Court should find appropriate, including the costs of abatement and disgorgement of illicit proceeds;
- D. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law;
- E. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiffs; and
- F. Award such further and additional relief as the Court may deem just and proper under the circumstances.

**XIII. JURY DEMAND**

Plaintiffs demand a trial by jury on all issues so triable.

Dated: May 11, 2021

Respectfully Submitted,

**RUPP BAASE PFALZGRAF  
CUNNINGHAM LLC**

Attorneys for Plaintiffs

By: 

Marco Cercone, Esq.

Arthur N. Bailey, Esq.

1600 Liberty Building

Buffalo, NY 14202

(716)854-3400

[cercone@ruppbaase.com](mailto:cercone@ruppbaase.com)

[bailey@ruppbaase.com](mailto:bailey@ruppbaase.com)

Additional Counsel for Plaintiffs Who Will Seek Admission *Pro Hac Vice*:

John W. ("Don") Barrett

Sterling Starns

David McMullan, Jr.

**BARRETT LAW GROUP, PA**

P.O. Box 927

404 Court Square North

Lexington, MS 39095

Tel: (662) 834-2488

Fax: (662) 834-2628

[dbarrett@barrettlawgroup.com](mailto:dbarrett@barrettlawgroup.com)

[sstarns@barrettlawgroup.com](mailto:ssstarns@barrettlawgroup.com)

[dmcmullan@barrettlawgroup.com](mailto:dmcmullan@barrettlawgroup.com)

Warren Burns

Darren Nicholson

**BURNS CHAREST, LLP**

900 Jackson St., Suite 500

Dallas, Texas 75202

Telephone: (469) 904-4550

Facsimile: (469) 444-5002

[wburns@burnscharest.com](mailto:wburns@burnscharest.com)

[dnicholson@burnscharest.com](mailto:dnicholson@burnscharest.com)

Korey A. Nelson  
 Rick Yelton  
 Patrick Murphree  
 Leila Abu-Orf

**BURNS CHAREST, LLP**

365 Canal Street, Suite 1170  
 New Orleans, LA 70130  
 Telephone: (504) 799-2845  
 Facsimile: (504) 881-1765  
[knelson@burnscharest.com](mailto:knelson@burnscharest.com)  
[ryelton@burnscharest.com](mailto:ryelton@burnscharest.com)  
[pmurphree@burnscharest.com](mailto:pmurphree@burnscharest.com)  
[labuorf@burnscharest.com](mailto:labuorf@burnscharest.com)

Jonathan W. Cuneo  
 Monica Miller  
 Mark H. Dubester  
 David L. Black  
 Jennifer E. Kelly  
 Evelyn Li

**CUNEO GILBERT & LADUCA, LLP**

4725 Wisconsin Avenue, NW, Suite 200  
 Washington, DC 20016  
 Telephone: (202) 789-3960  
[jonc@cuneolaw.com](mailto:jonc@cuneolaw.com)  
[monicam@cuneolaw.com](mailto:monicam@cuneolaw.com)  
[mark@cuneolaw.com](mailto:mark@cuneolaw.com)  
[dblack@cuneolaw.com](mailto:dblack@cuneolaw.com)  
[jkelly@cuneolaw.com](mailto:jkelly@cuneolaw.com)  
[evelyn@cuneolaw.com](mailto:evelyn@cuneolaw.com)

Steve Martino  
**TAYLOR MARTINO, P.C.**  
 51 St. Joseph St.  
 Mobile, AL 36602  
 Telephone: (251) 433-3131  
[SteveMartino@taylormartino.com](mailto:SteveMartino@taylormartino.com)

Gerald M. Abdalla, Jr.  
**ABDALLA LAW, PLLC**  
 602 Steed Road, Suite 200  
 Ridgeland, Mississippi 39157  
 Telephone: (601) 487-4590  
[jerry@abdalla-law.com](mailto:jerry@abdalla-law.com)

*Attorneys for Plaintiffs*